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Overes et al.

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(45) **Date of Patent: Apr. 19, 2016**

(54) **FEMORAL NECK FRACTURE IMPLANT**

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(73) Assignee: **DEPUY SYNTHES PRODUCTS, INC.**, Raynham, MA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

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(22) PCT Filed: **Nov. 19, 2012**

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§ 371 (c)(1),
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US 2014/0094803 A1 Apr. 3, 2014

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(51) **Int. Cl.**
A61B 17/56 (2006.01)
A61B 17/74 (2006.01)

(52) **U.S. Cl.**
CPC ***A61B 17/746*** (2013.01); ***A61B 17/74*** (2013.01)

(58) **Field of Classification Search**
CPC A61B 17/746; A61B 17/56; A61B 17/58; A61B 17/76; A61B 17/88
USPC 606/93, 280, 62–68, 96–99, 104, 916
See application file for complete search history.

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Primary Examiner — Jerry Cumberledge
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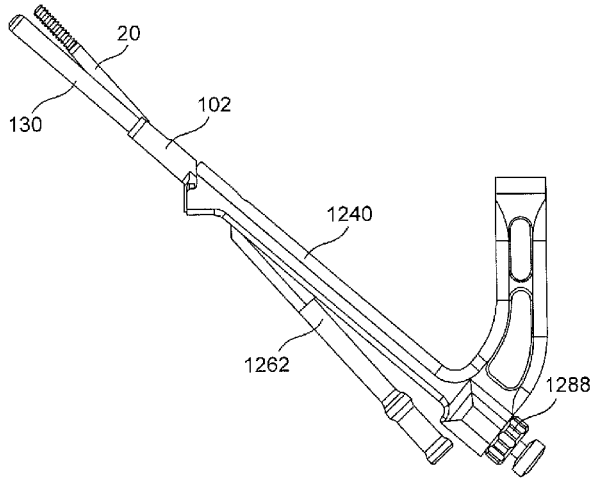
(57) **ABSTRACT**

A device for implanting a bone fixation system comprises an insertion instrument extending from a proximal end to a distal end, the distal end having an engagement portion for removably engaging a proximal end of a bone plate, the insertion instrument having an elongated channel extending therethrough to permit insertion of a first protection sleeve therethrough, wherein a longitudinal axis of the elongated channel is coaxial with a longitudinal axis of a first opening extending through the bone plate and a first protection sleeve insertable into the elongated channel and guiding insertion of an anti-rotation screw therethrough and through the bone plate, a longitudinal axis of the first protection sleeve being angled with respect to the longitudinal axis of the elongated channel.

20 Claims, 33 Drawing Sheets



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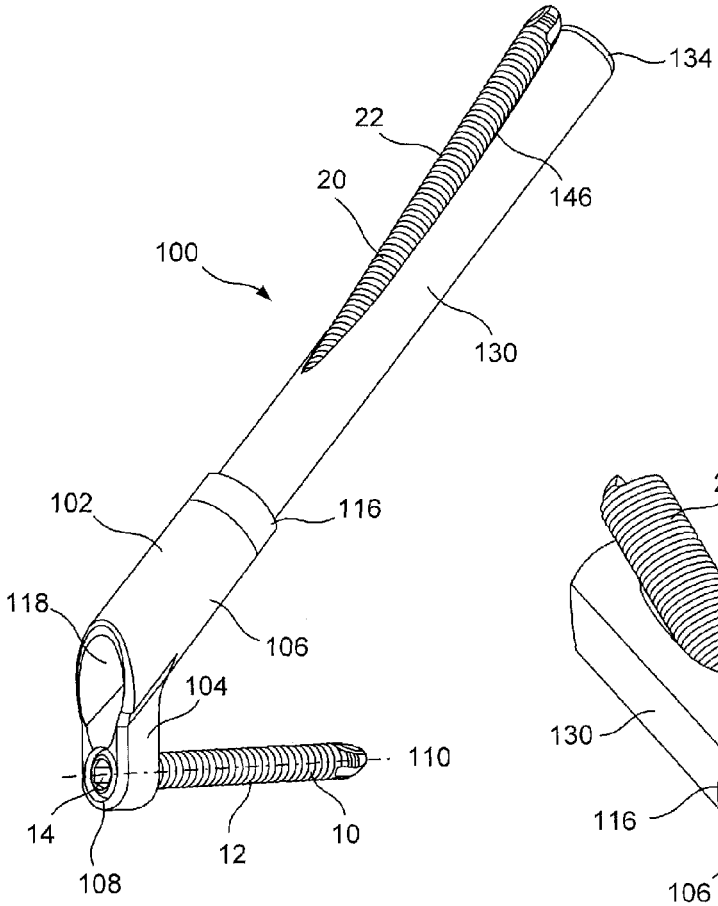
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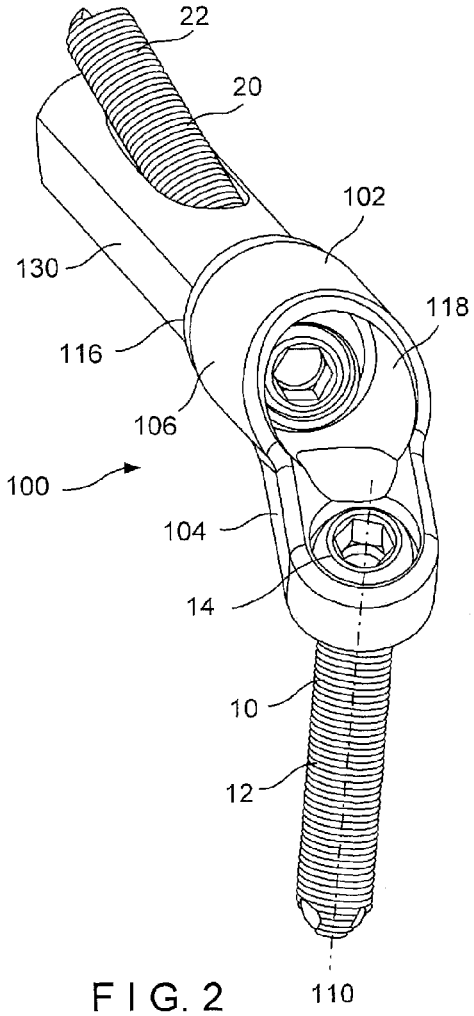
FIG. 1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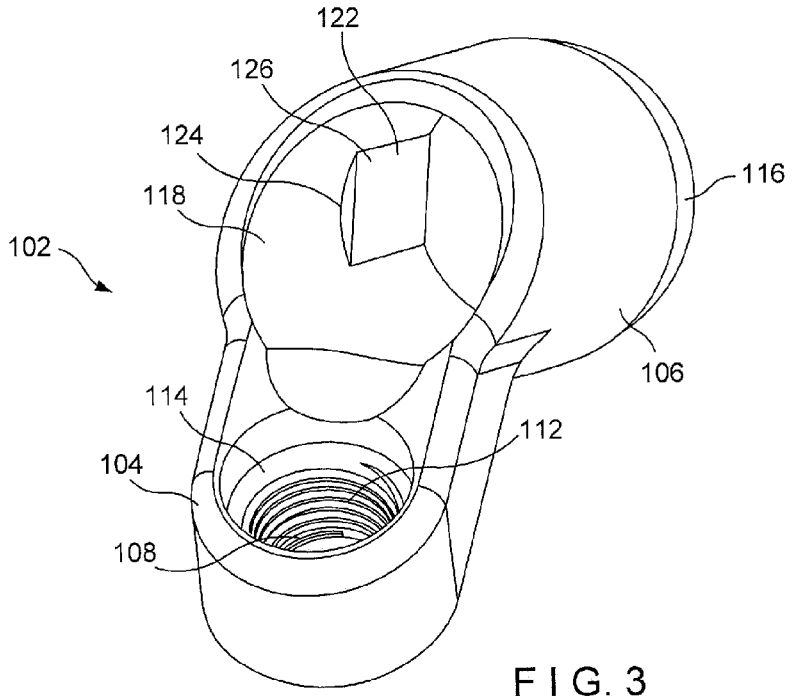
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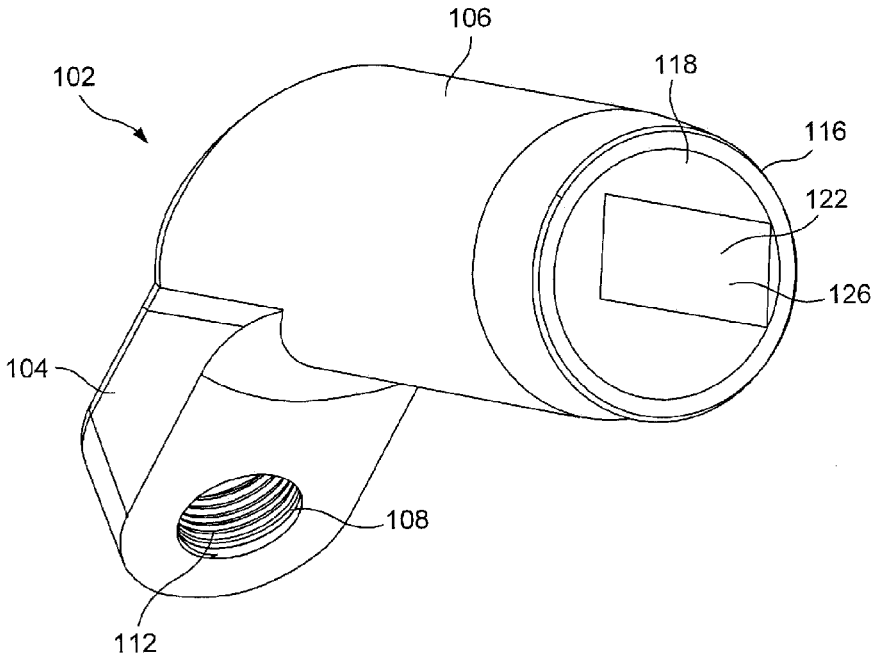
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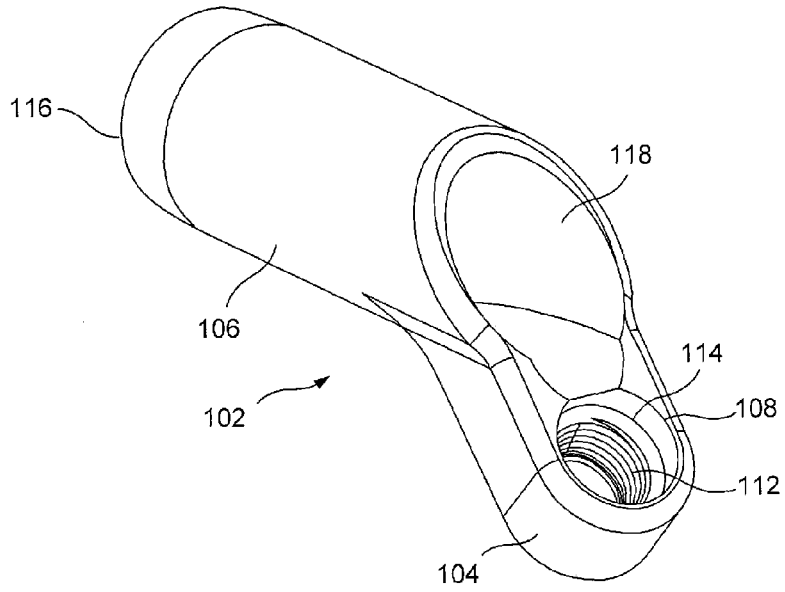
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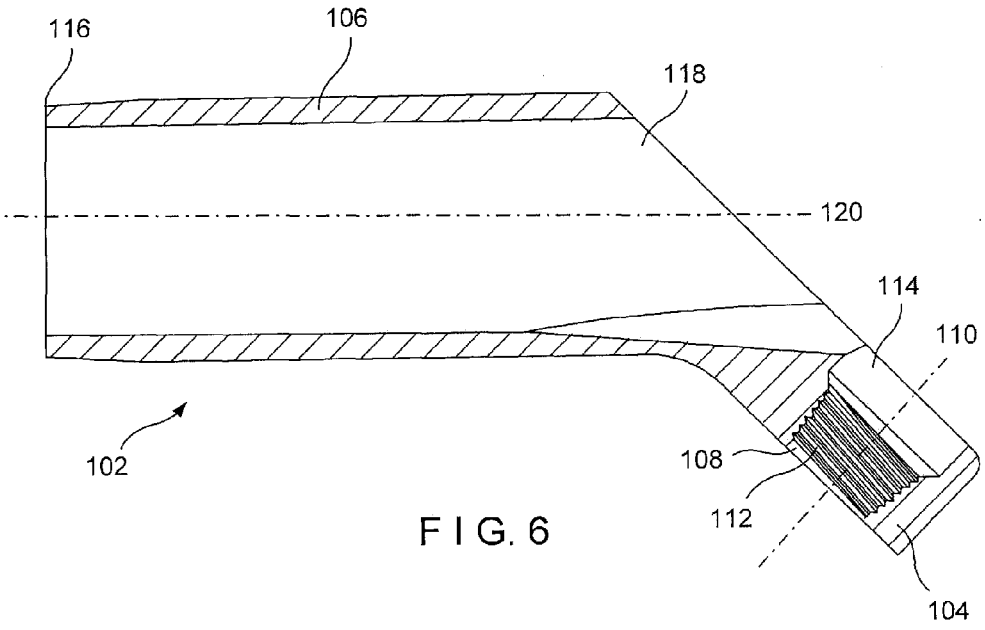
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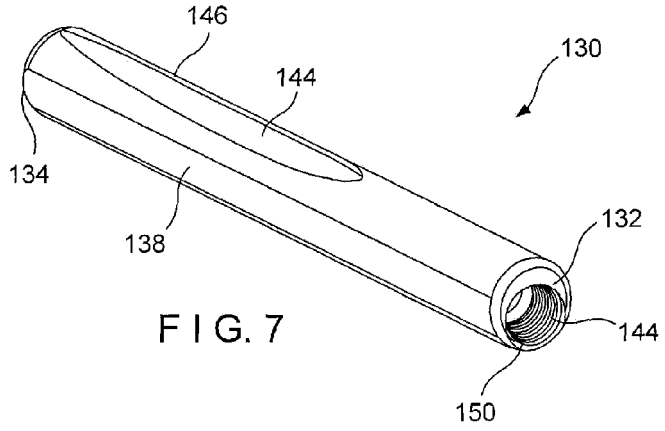

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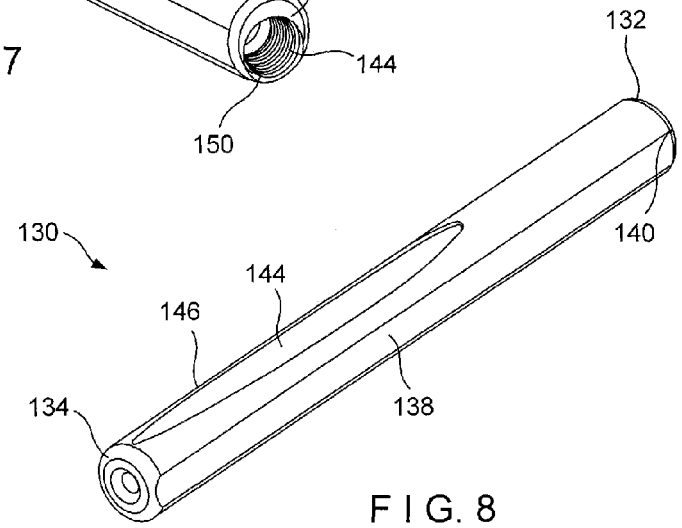

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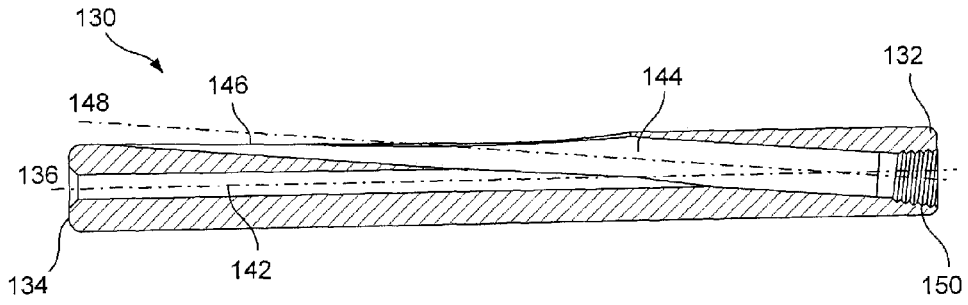

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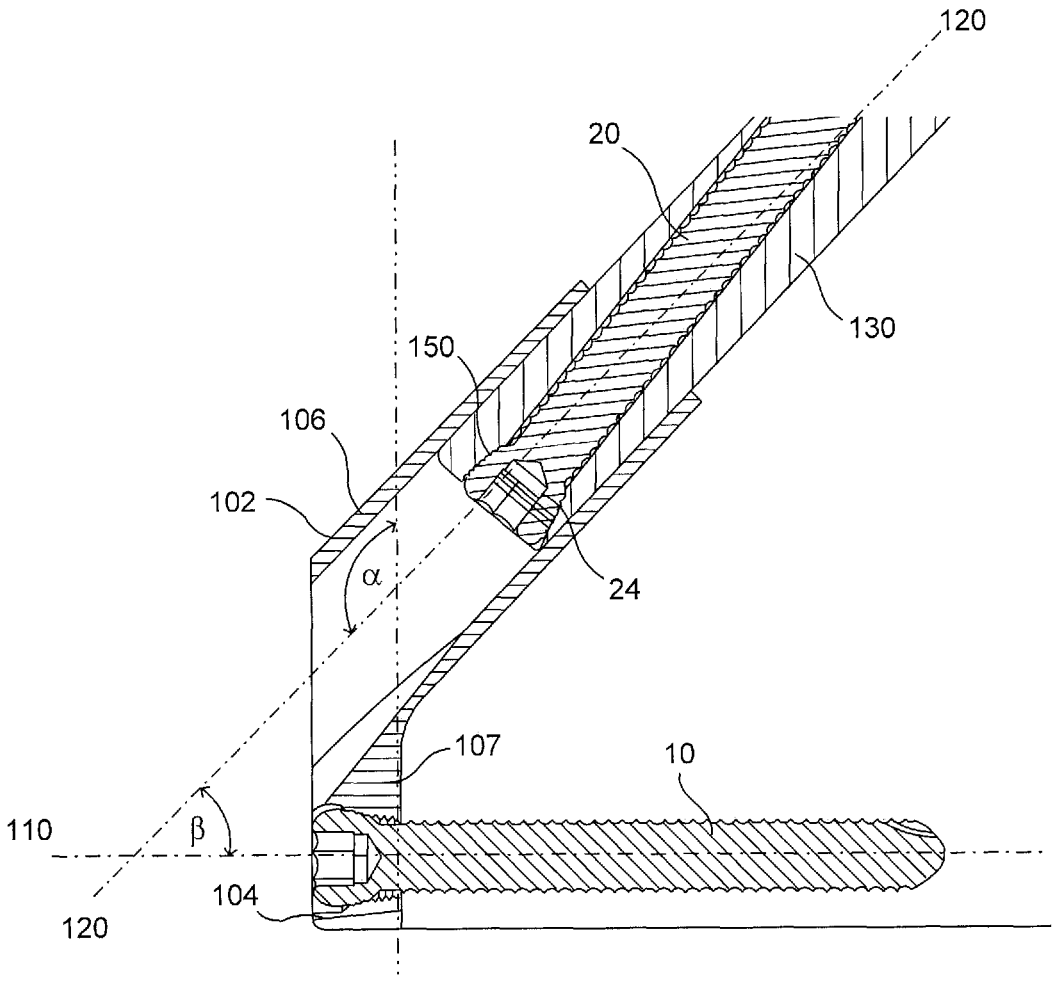

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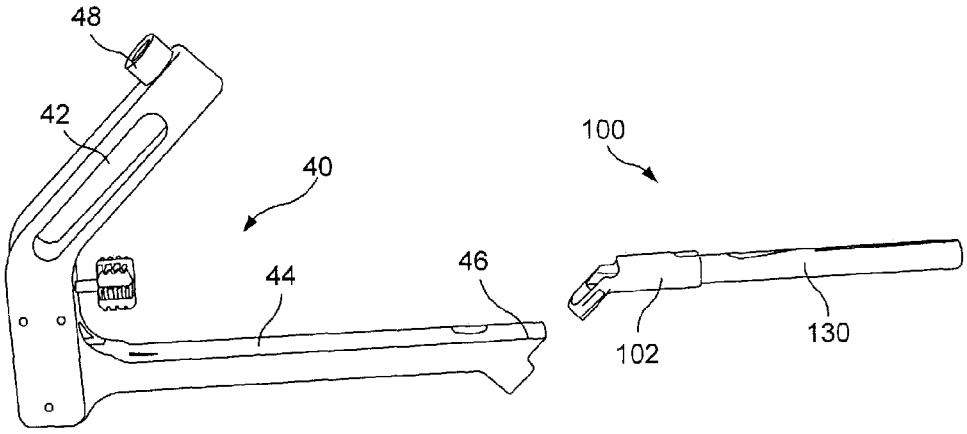

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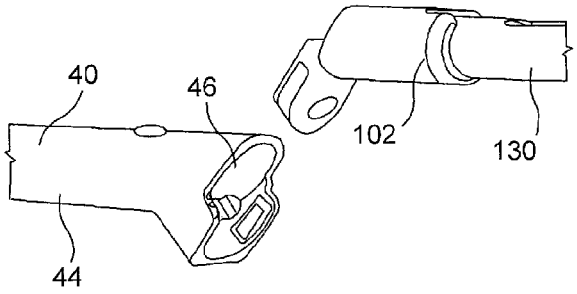

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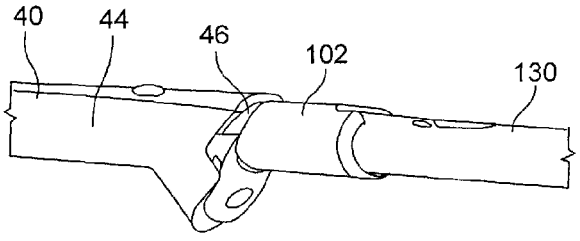

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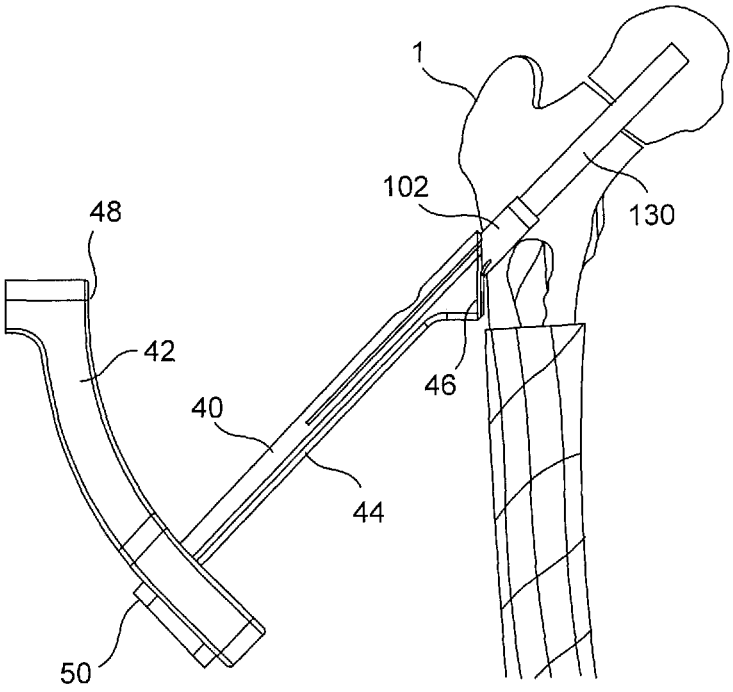

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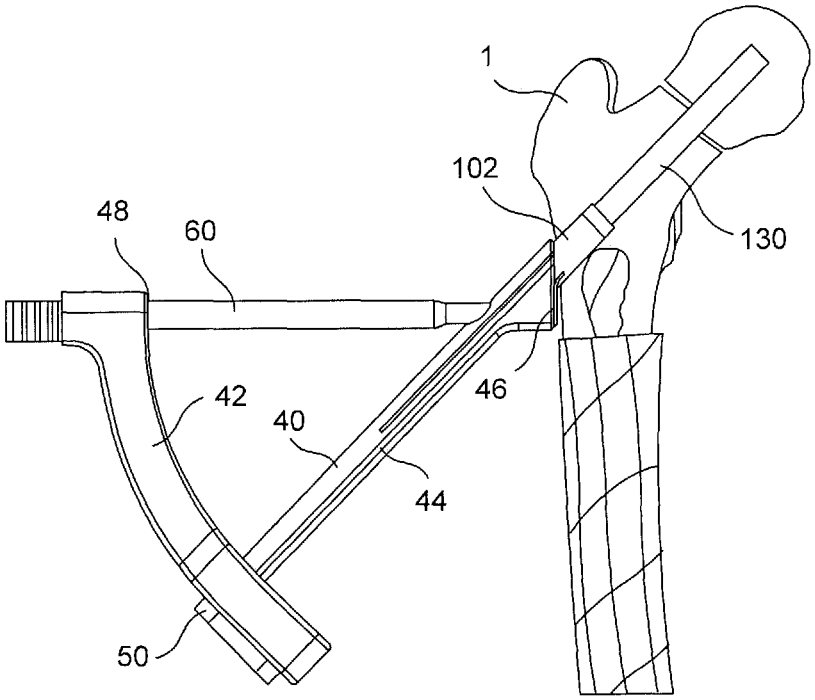

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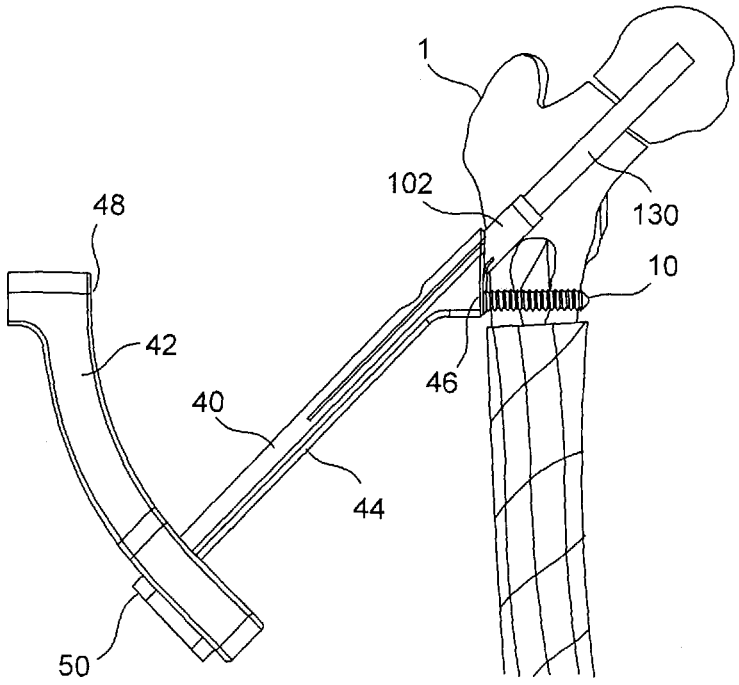

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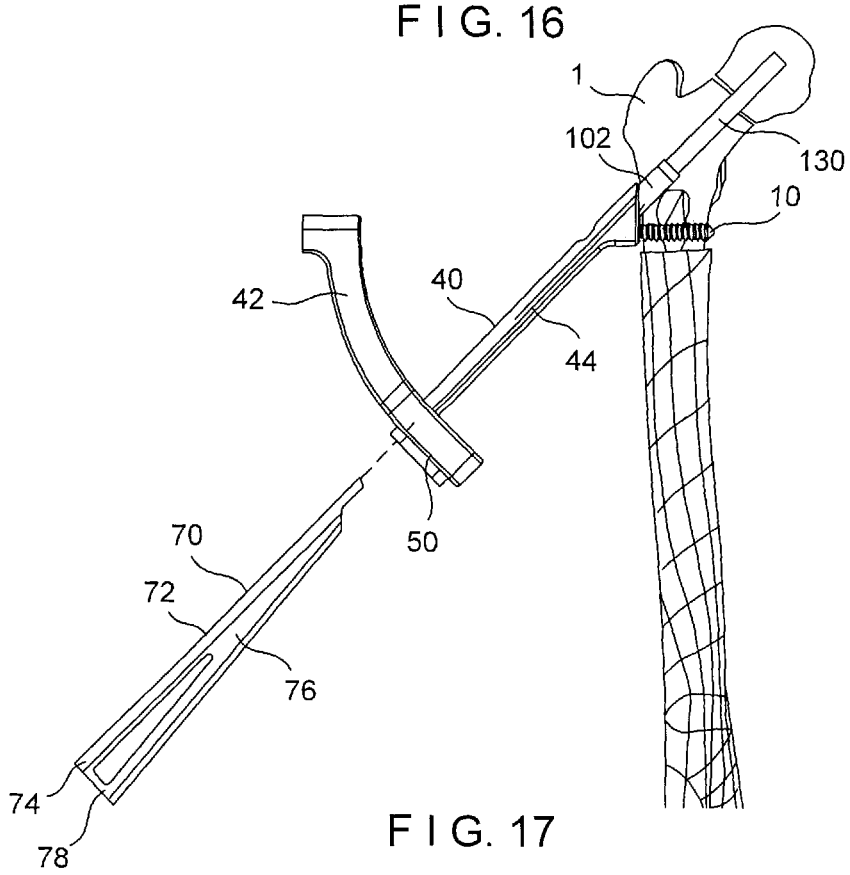

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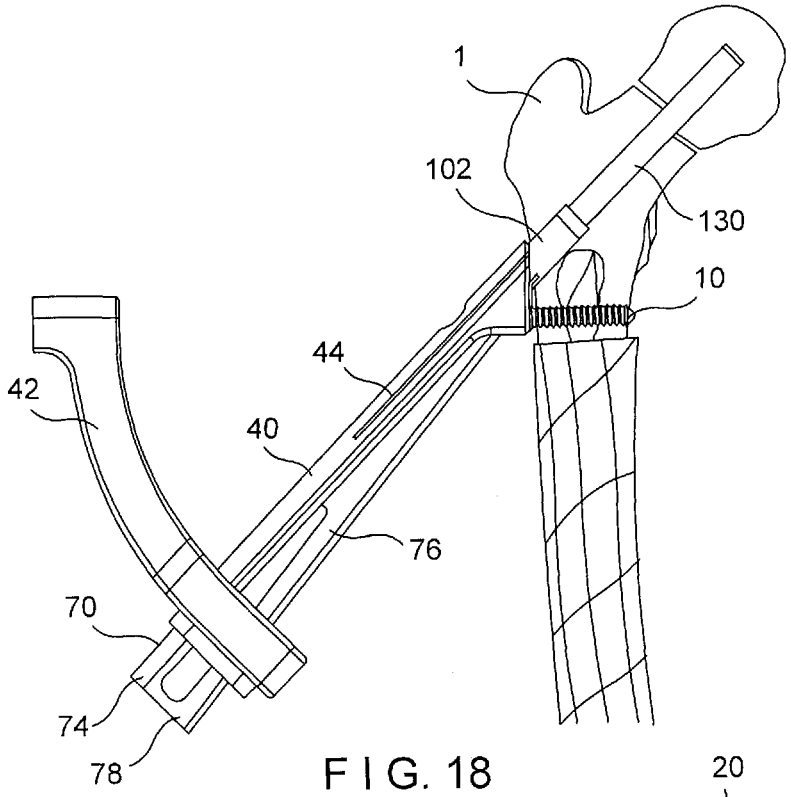

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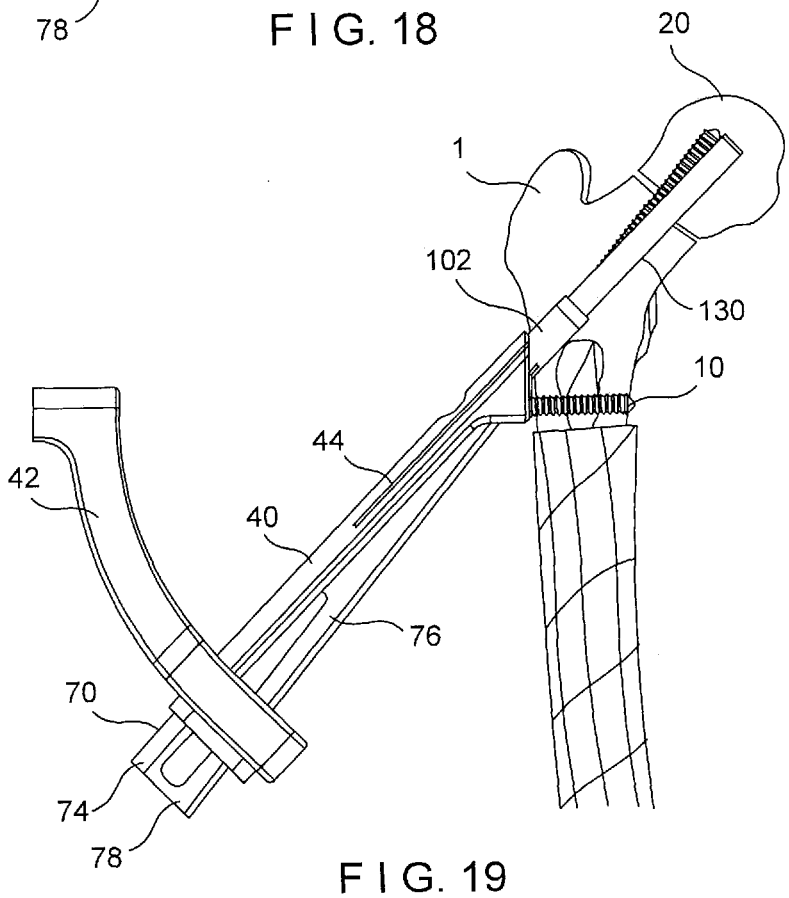

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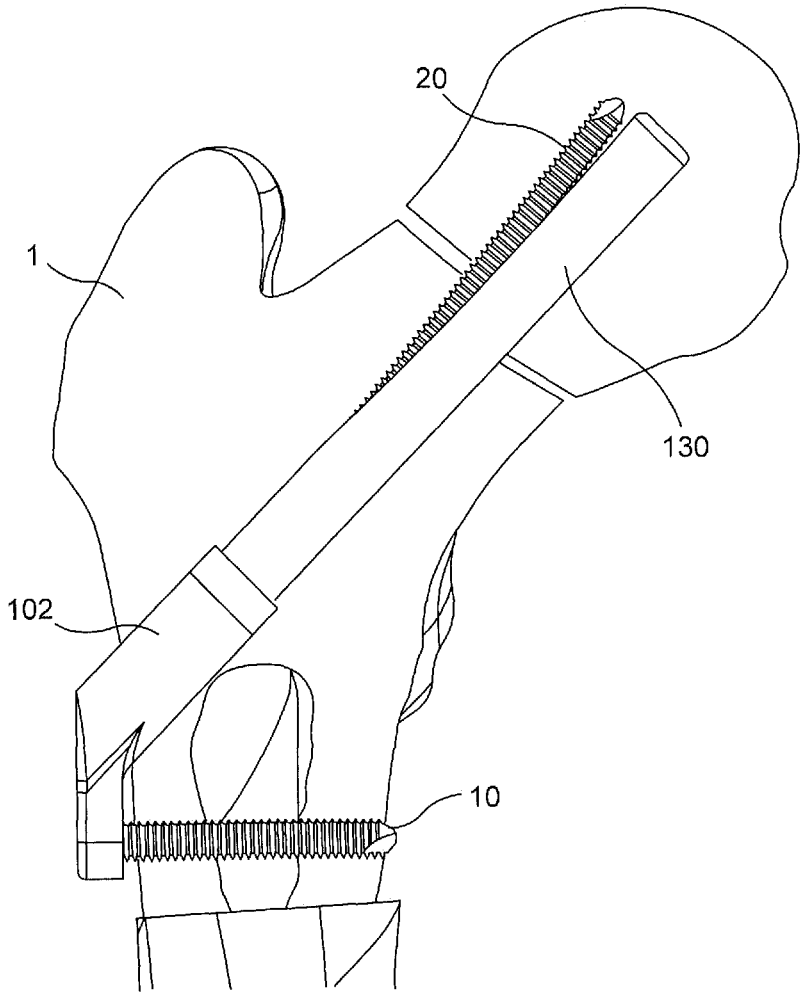

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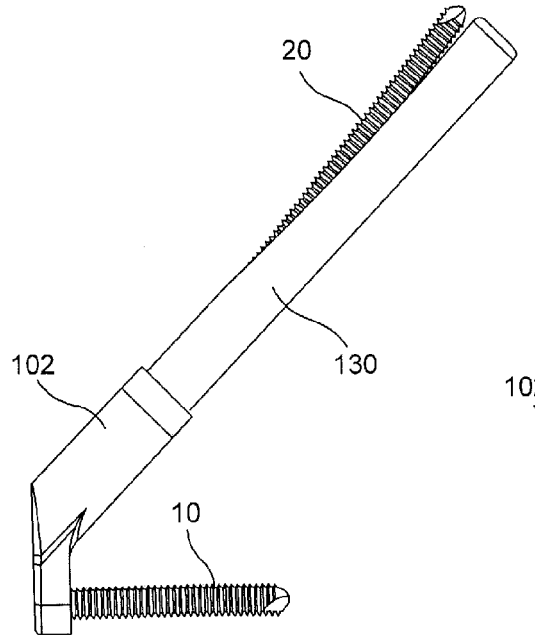

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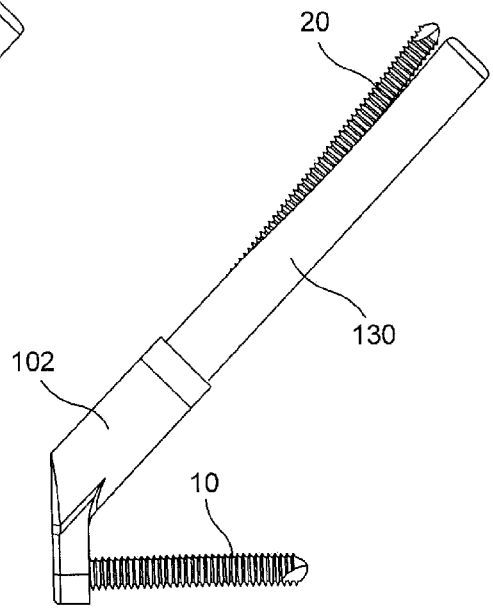

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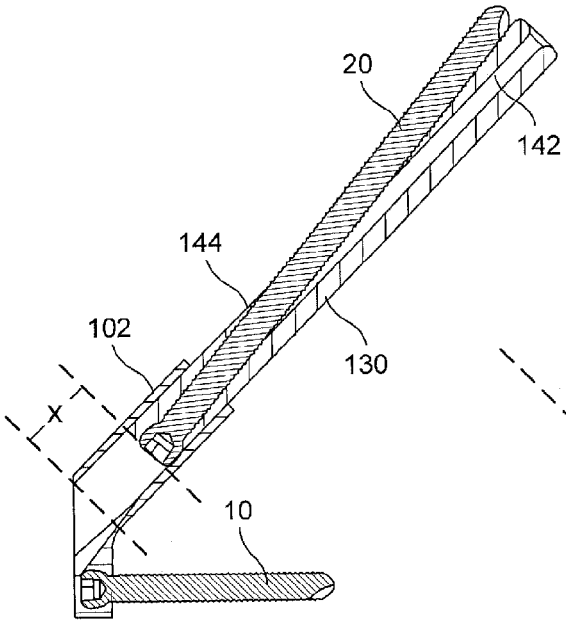

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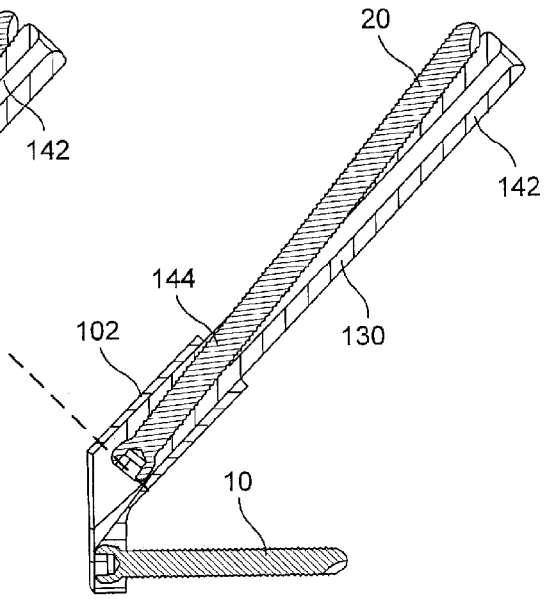

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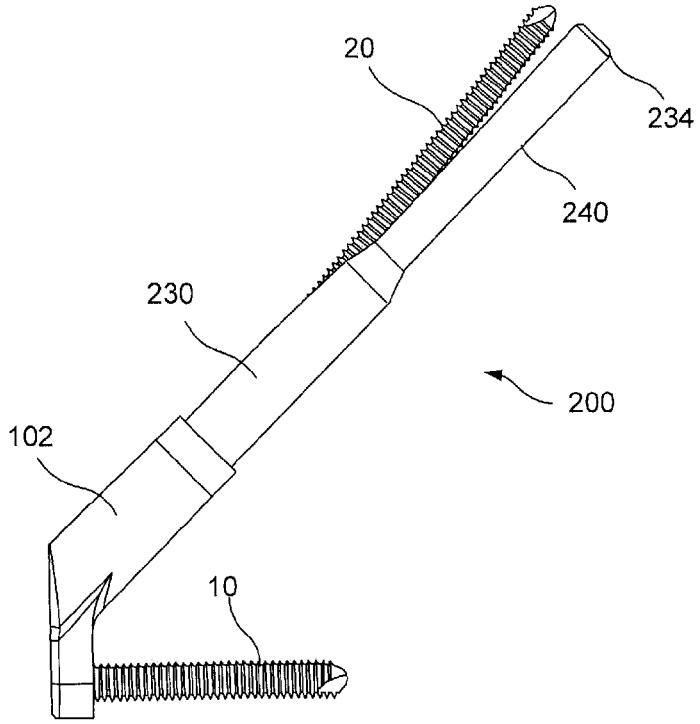

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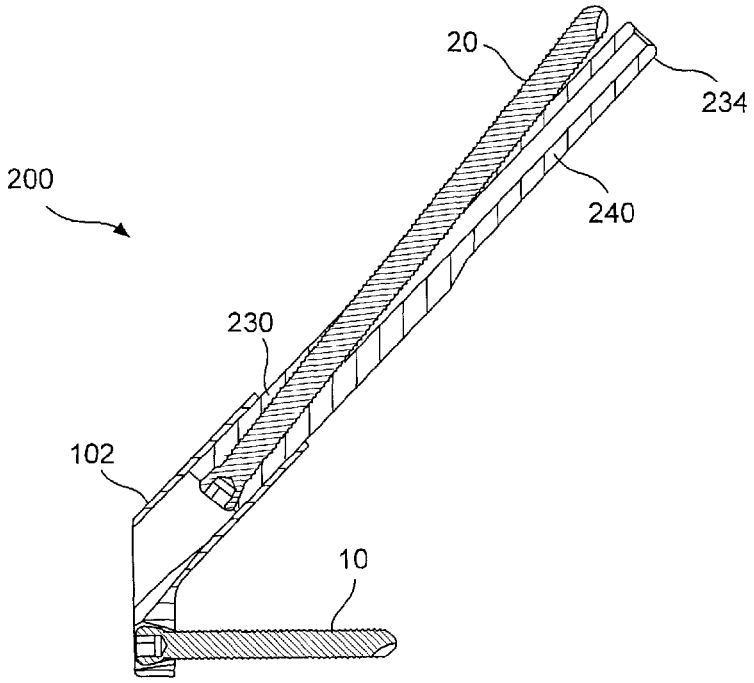

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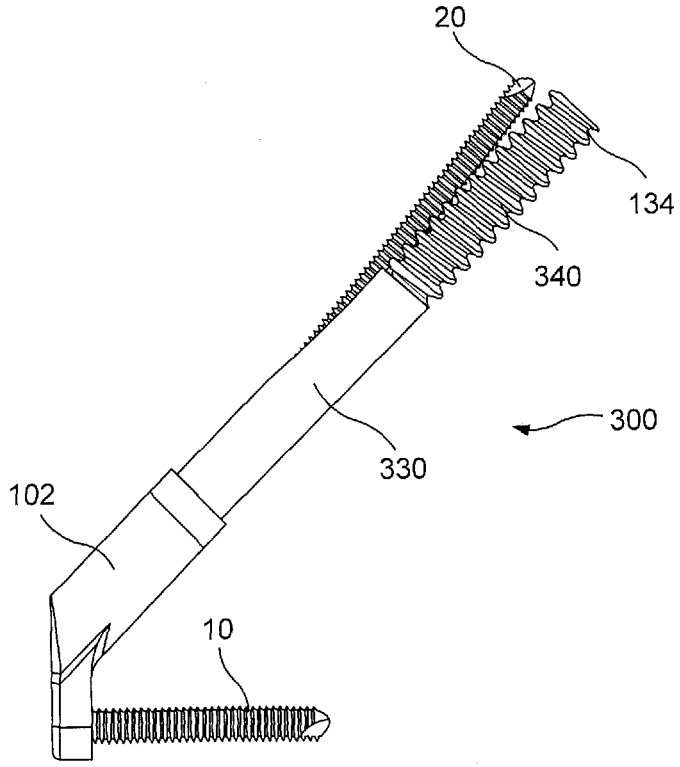

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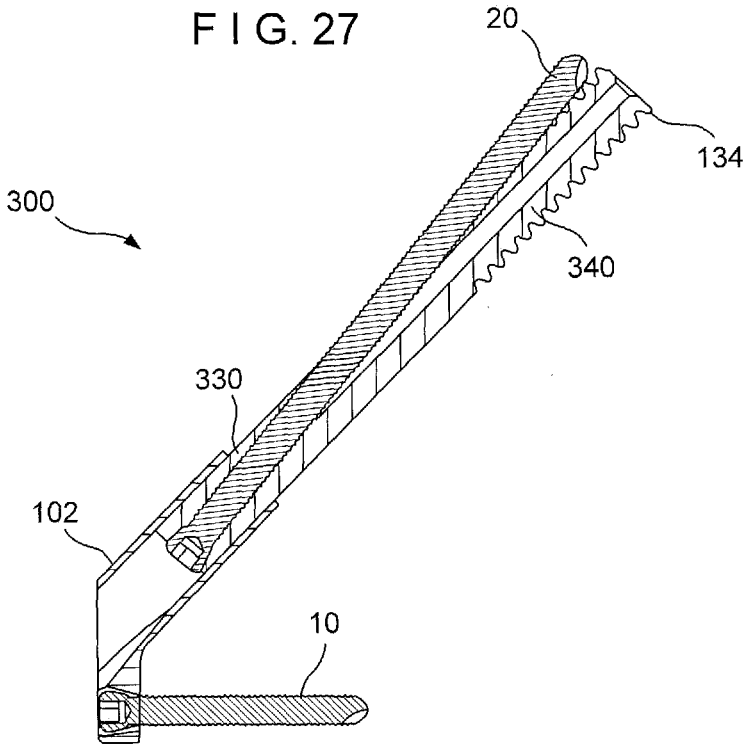

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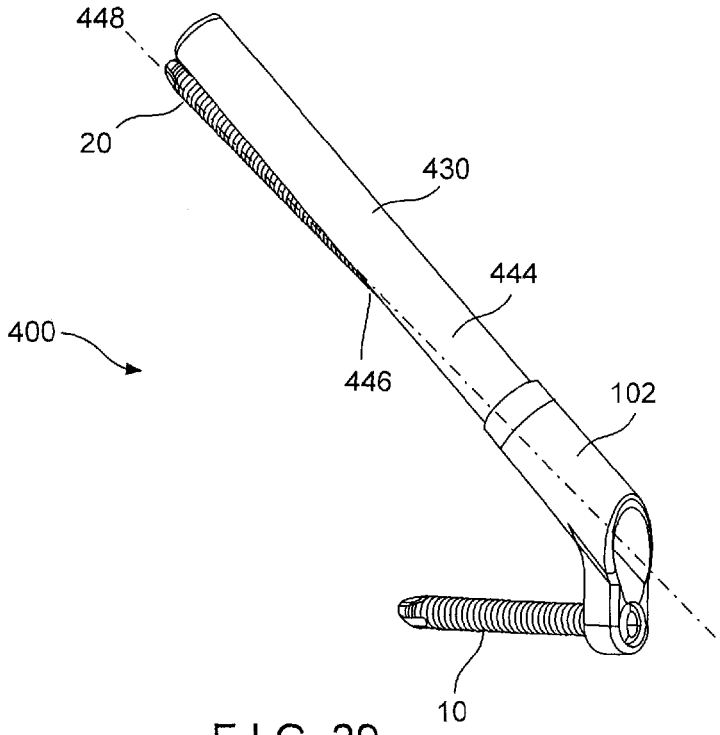

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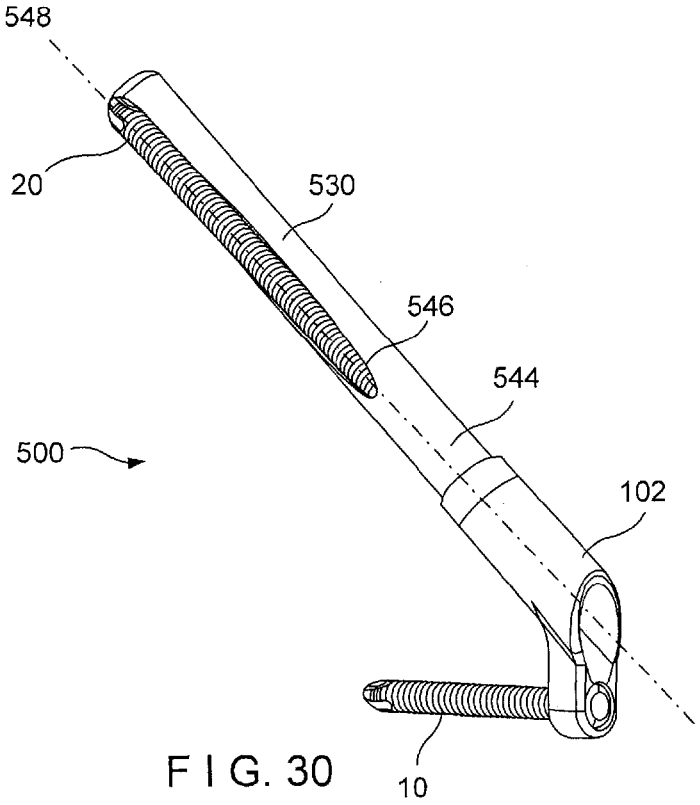

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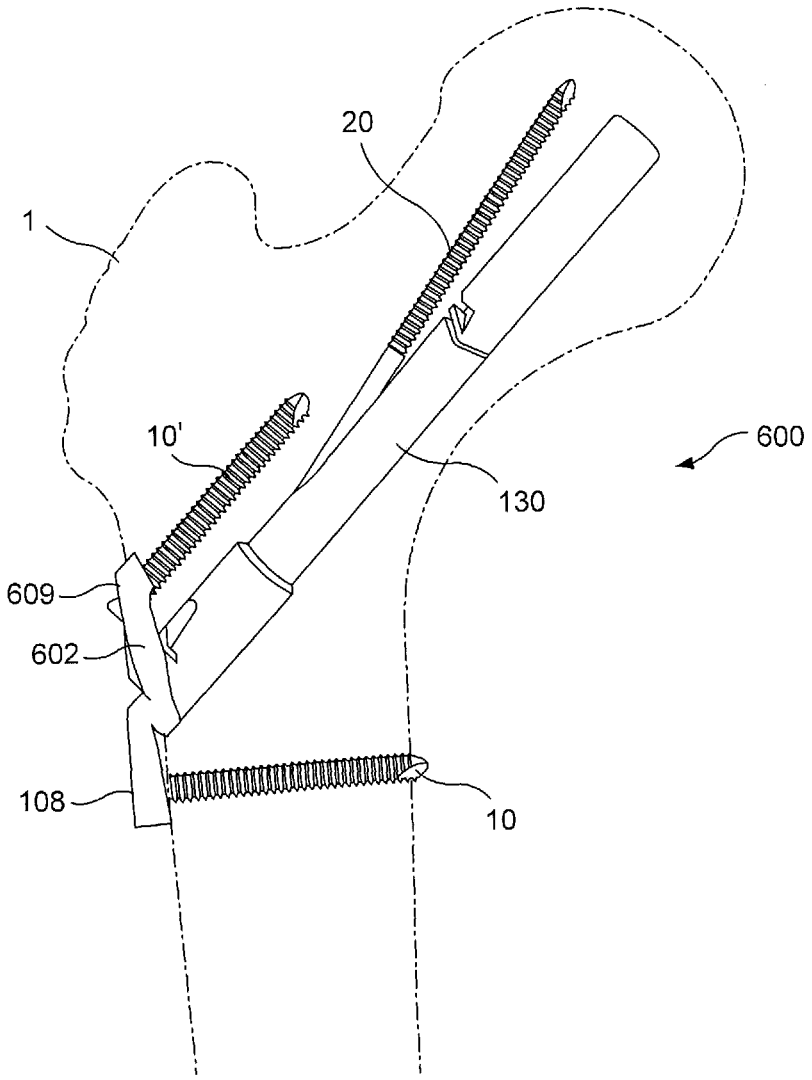

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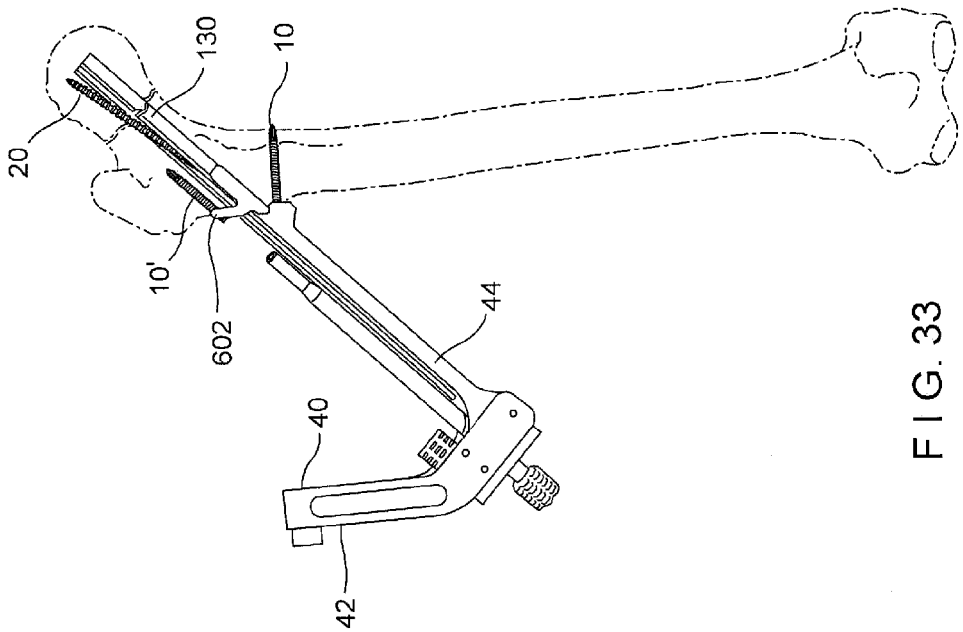

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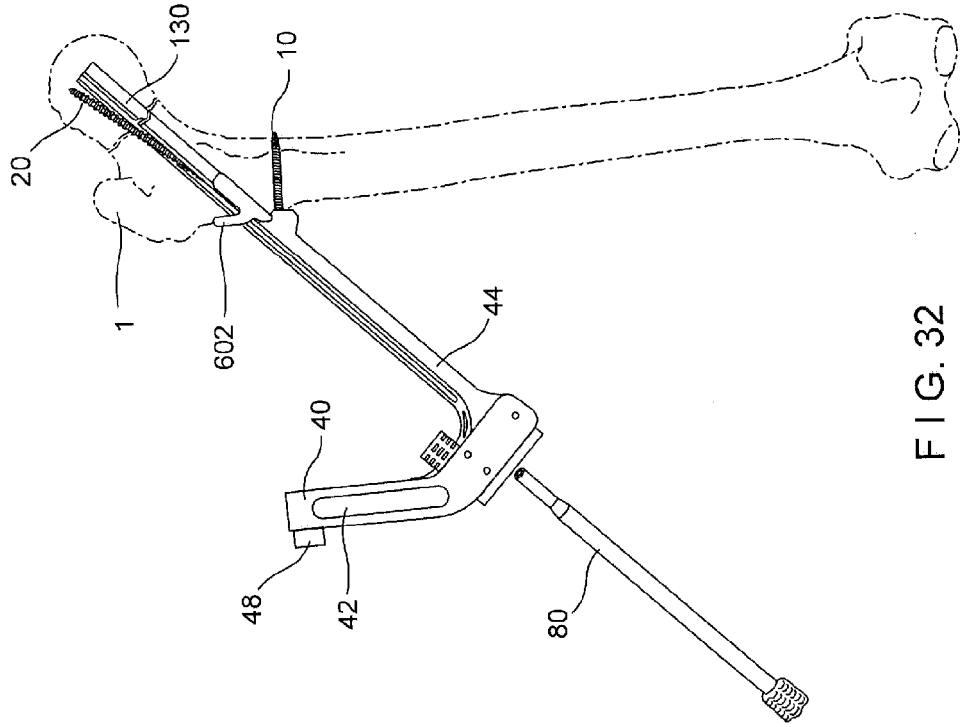

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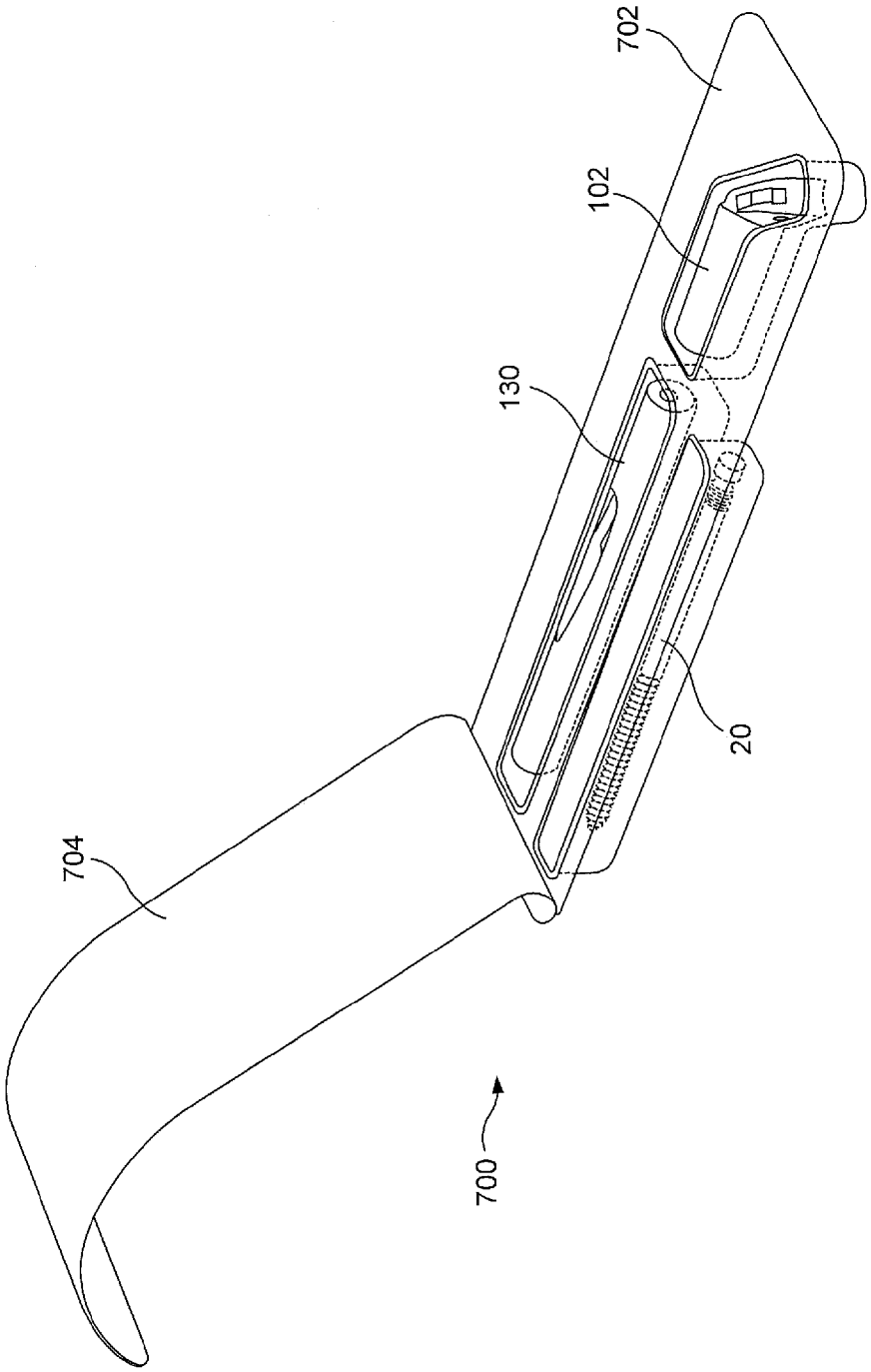

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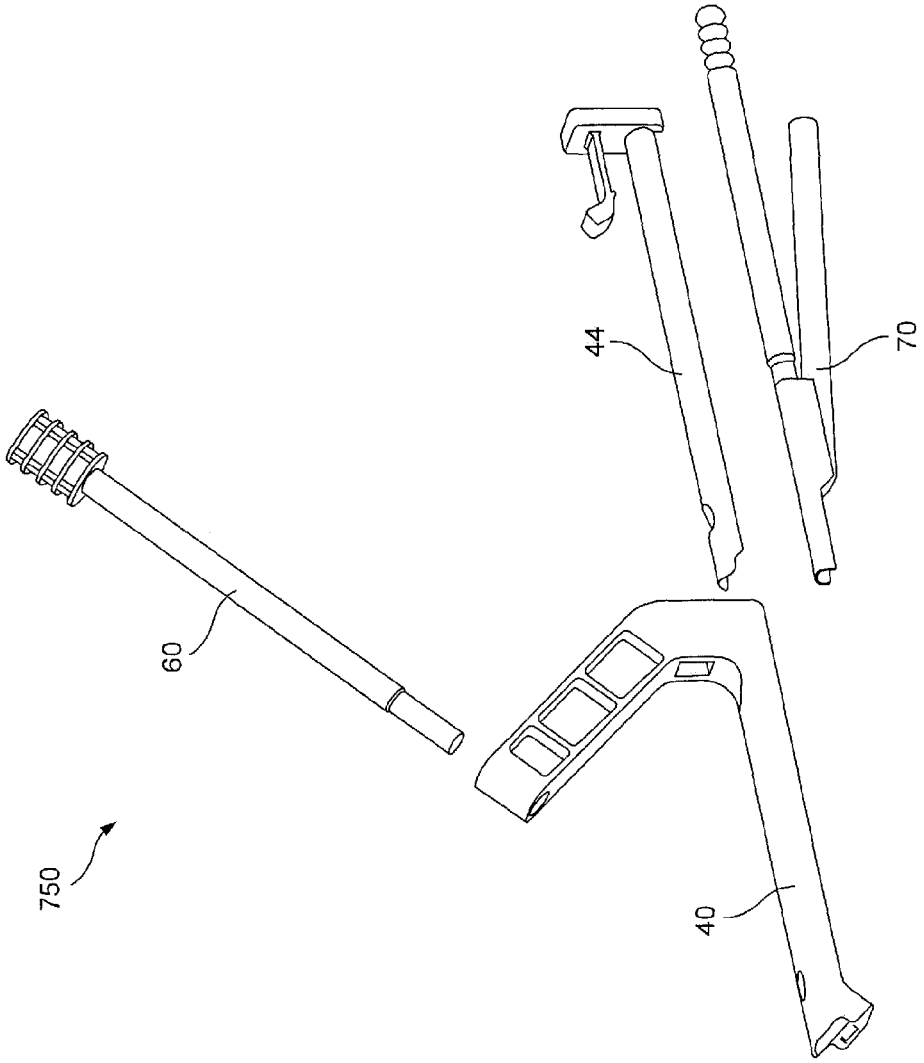

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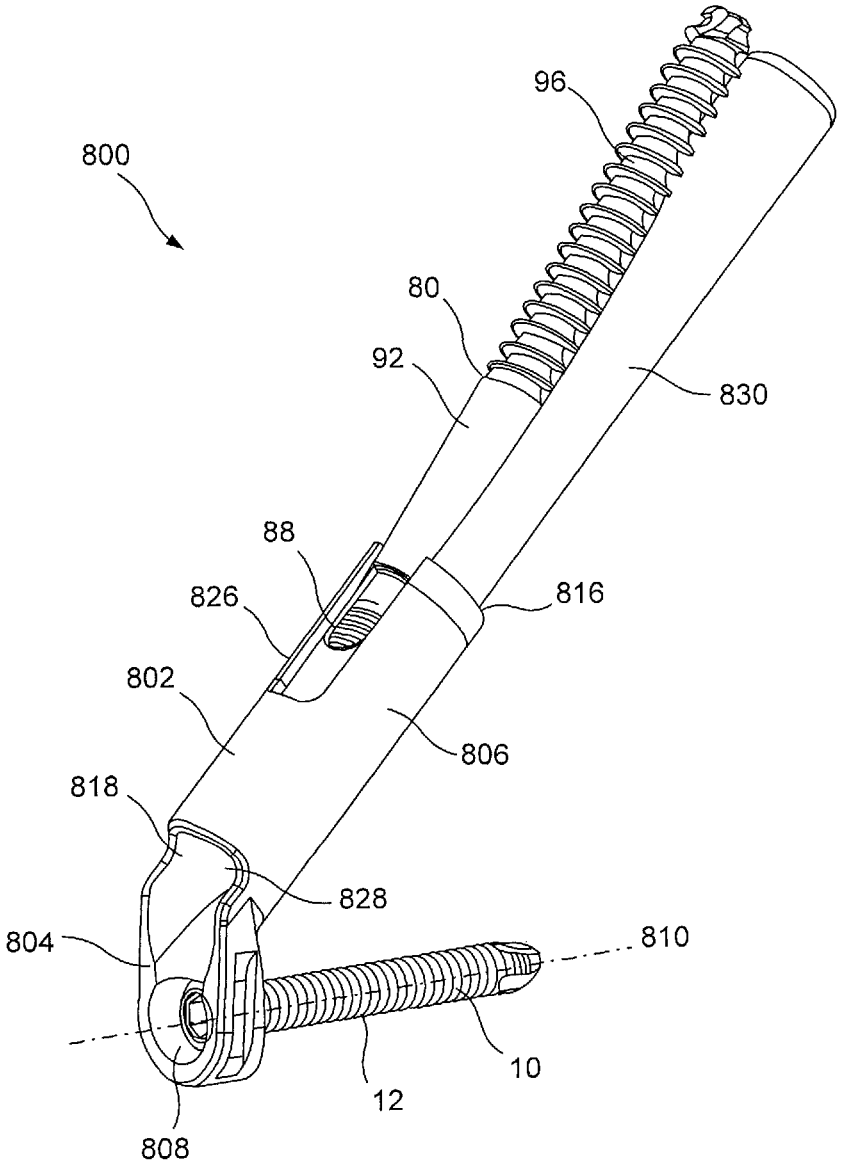

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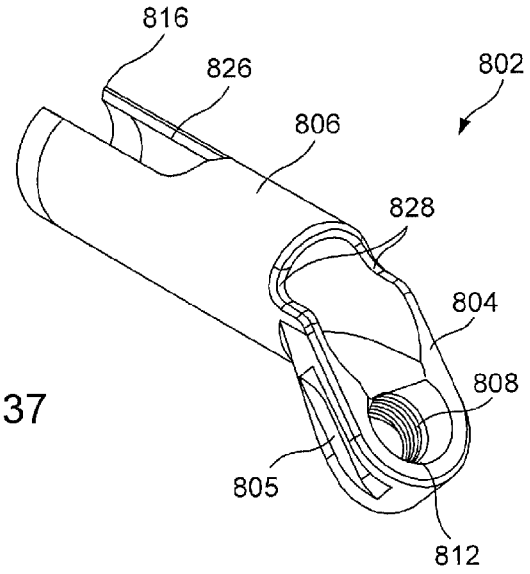

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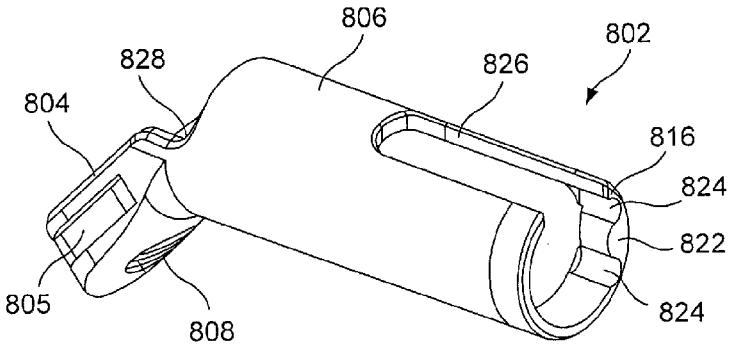

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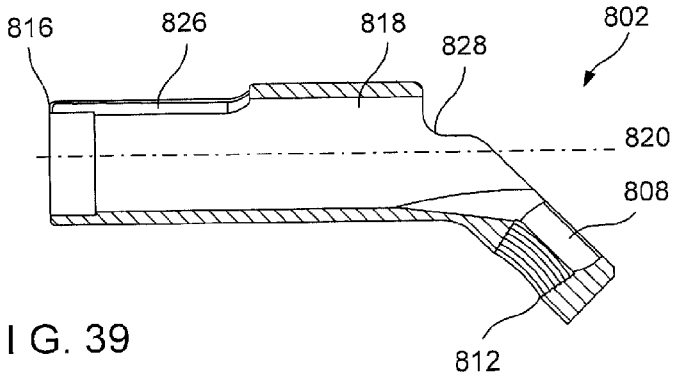

FIG. 39

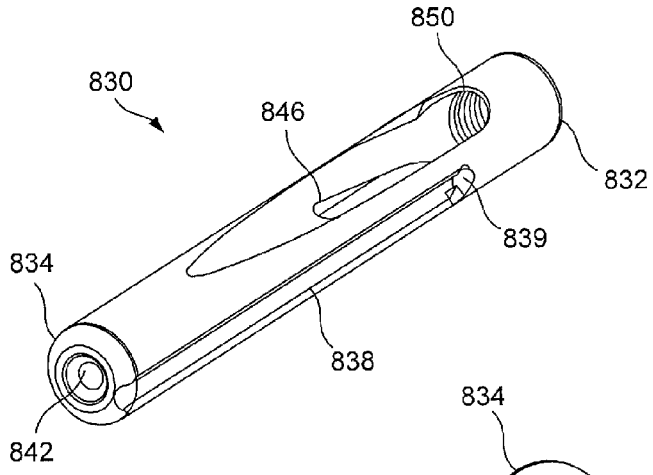

FIG. 40

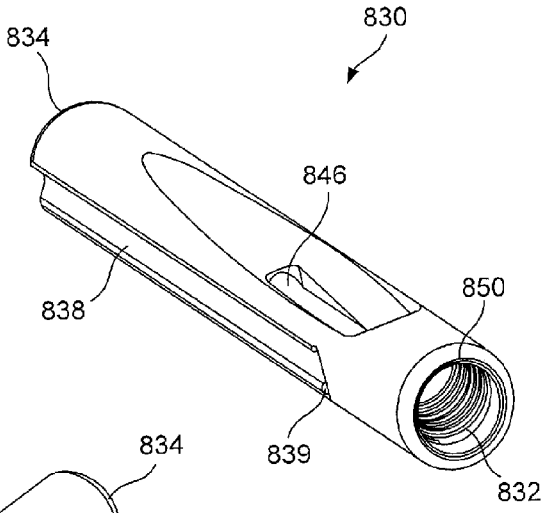

FIG. 41

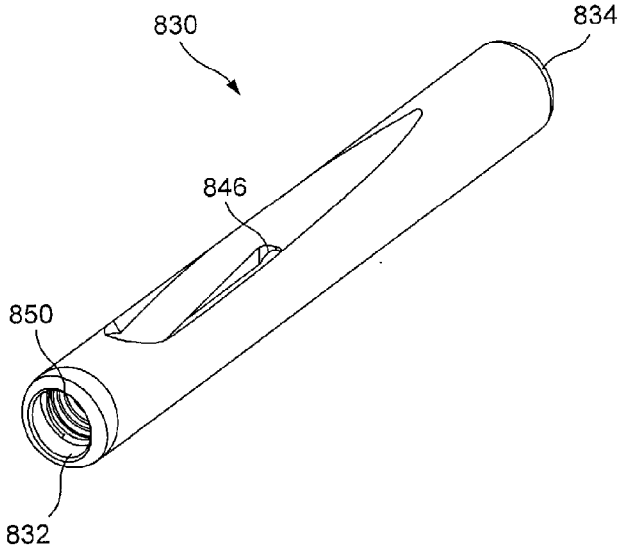

FIG. 42

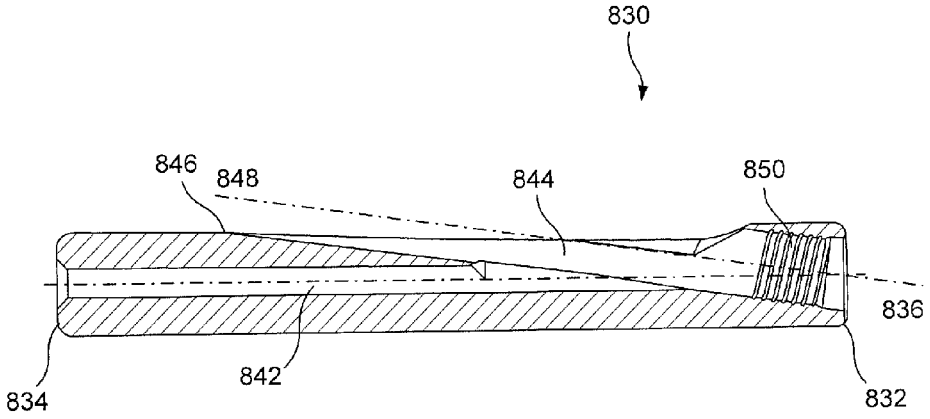

FIG. 43

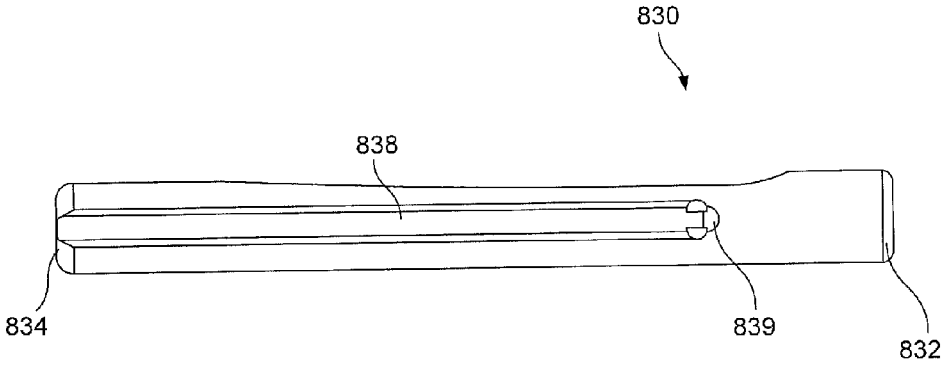

FIG. 44

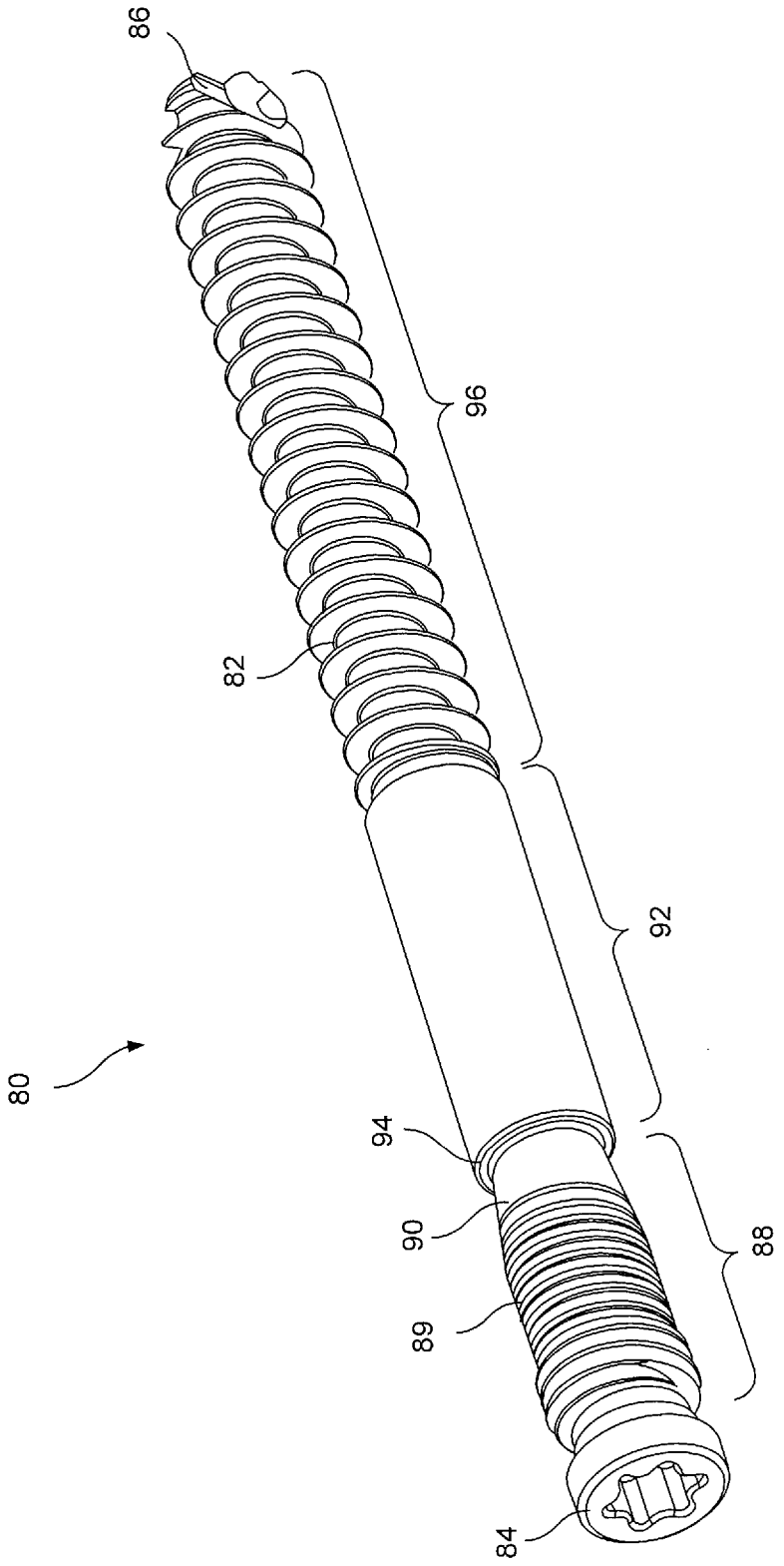

FIG. 45

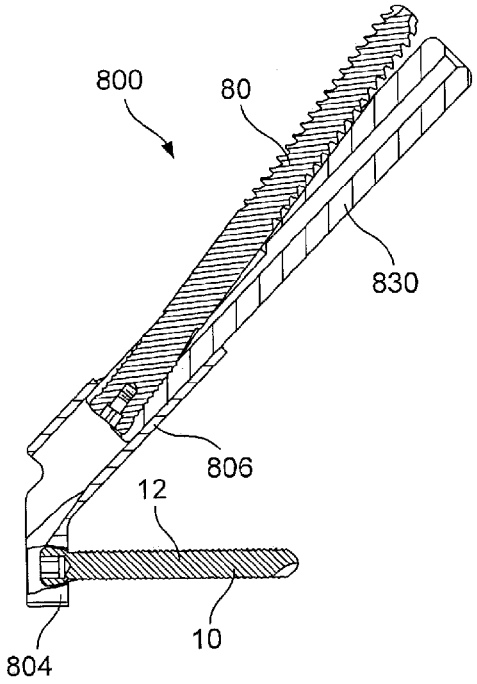

FIG. 46

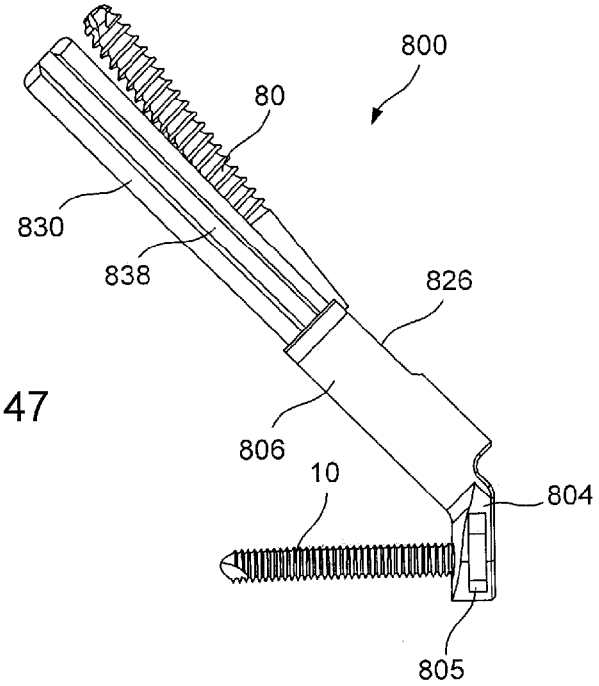

FIG. 47

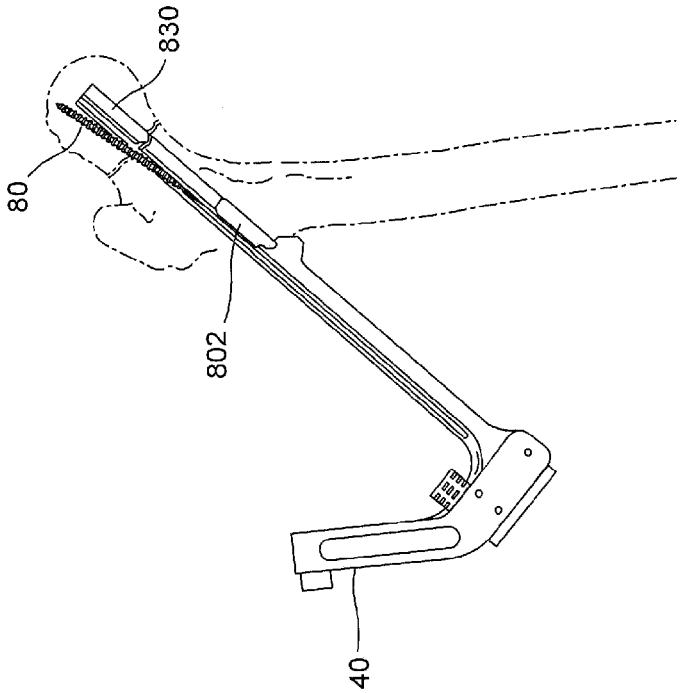

FIG. 49

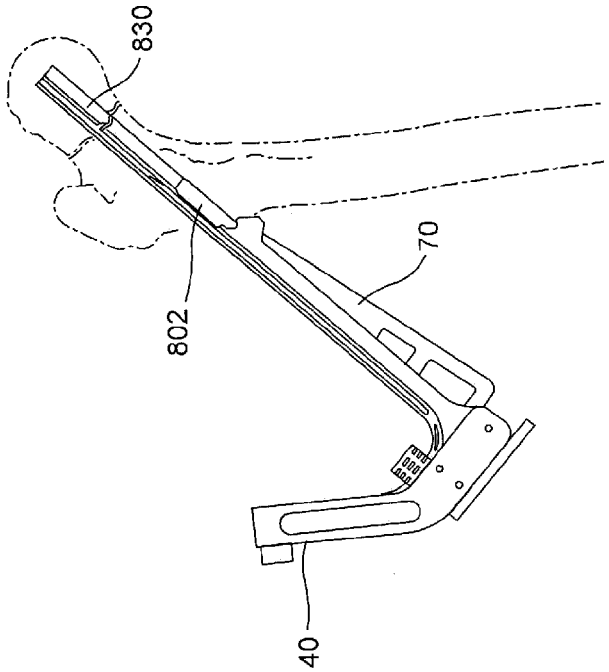

FIG. 48

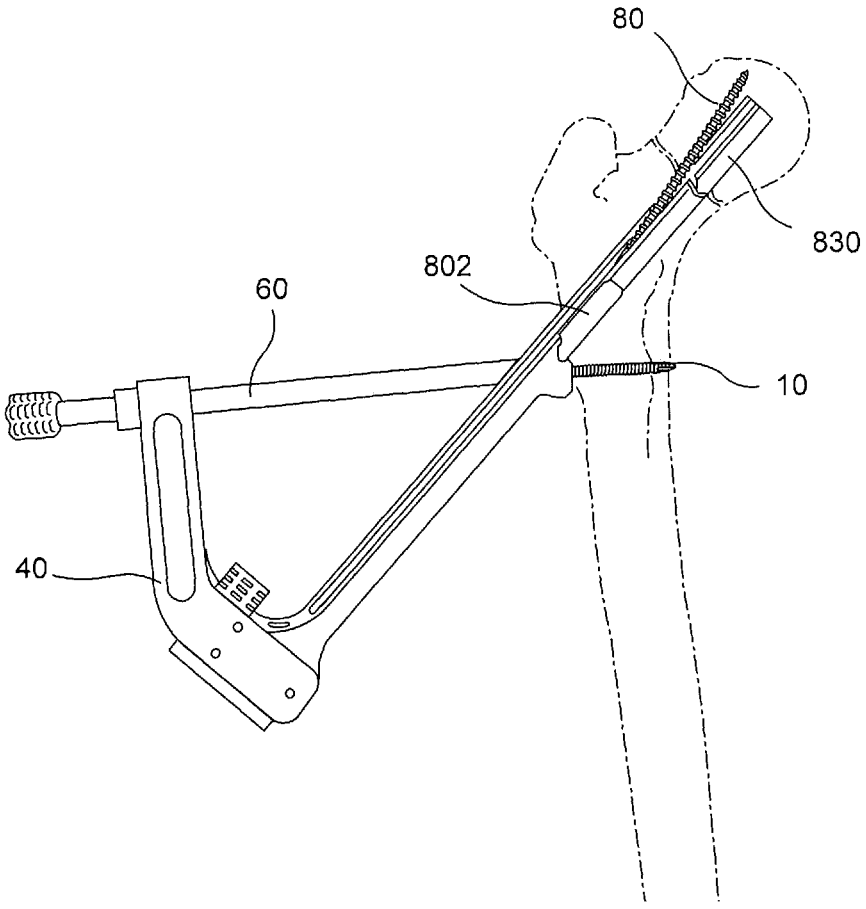

FIG. 50

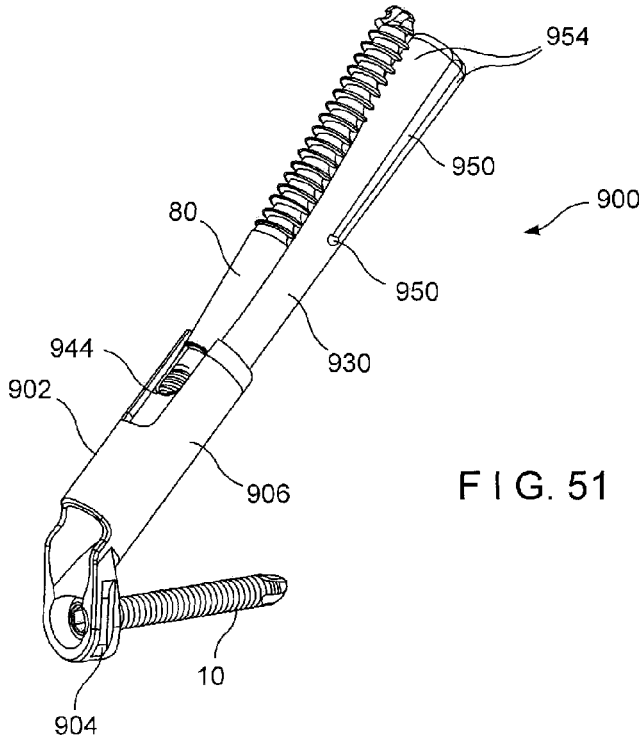
954
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FIG. 51

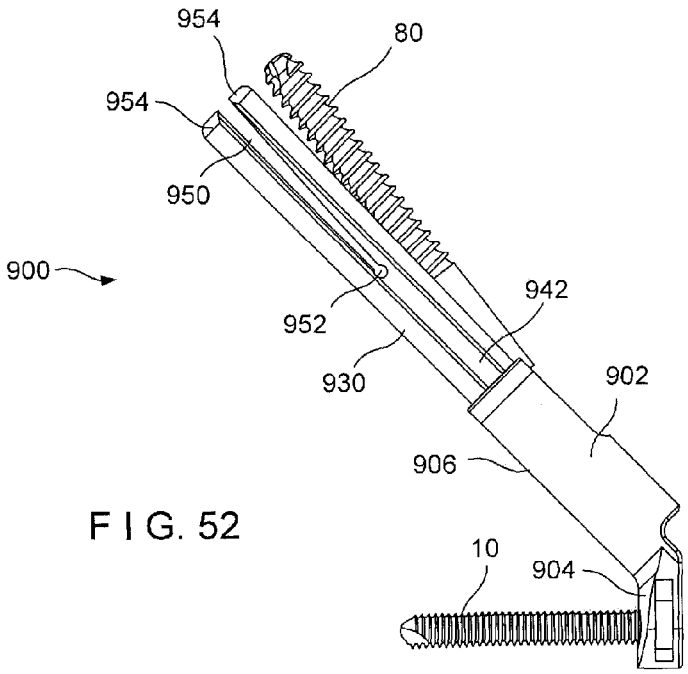
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FIG. 52

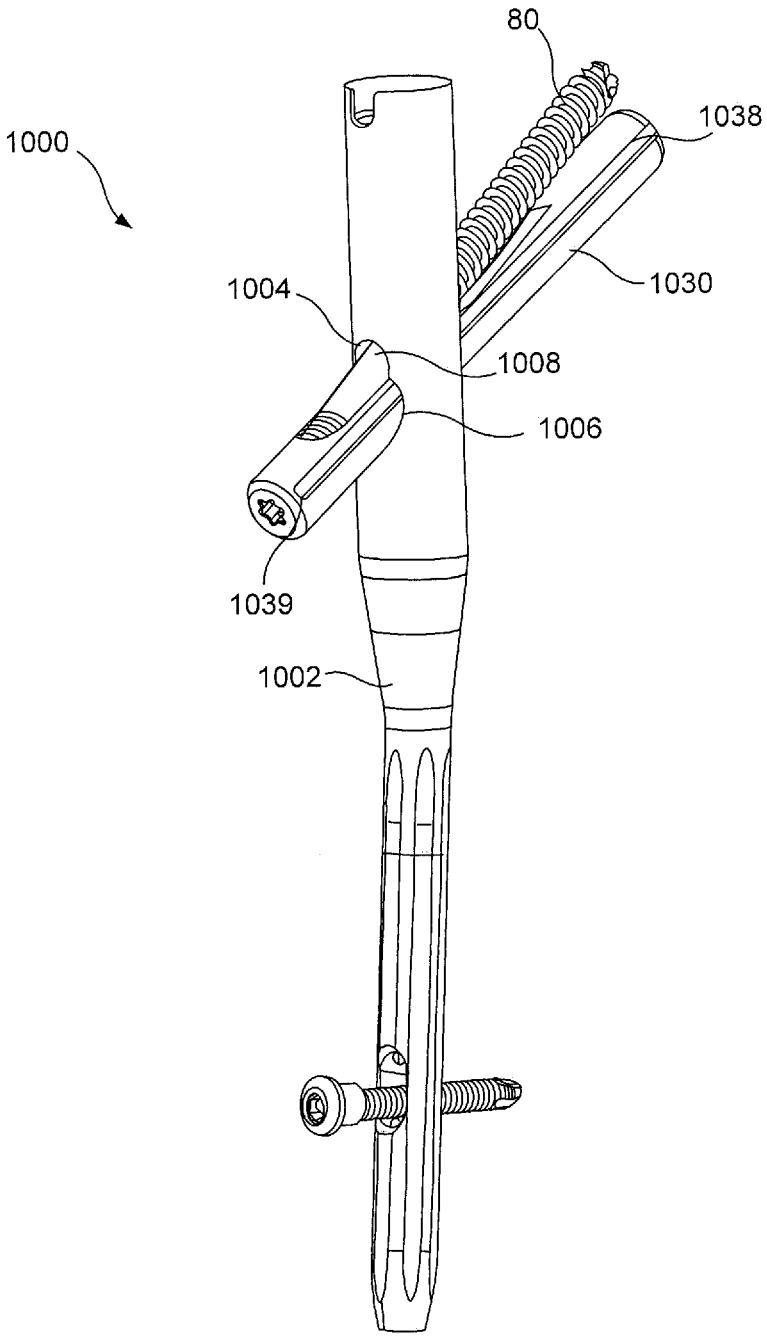

FIG. 53

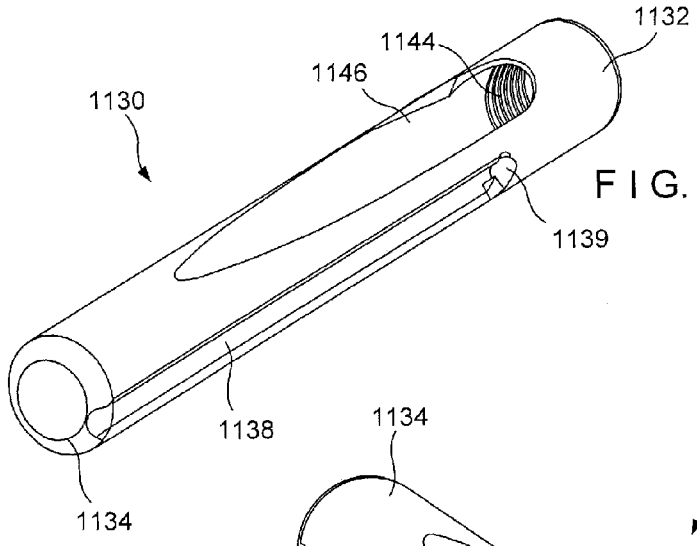

FIG. 54

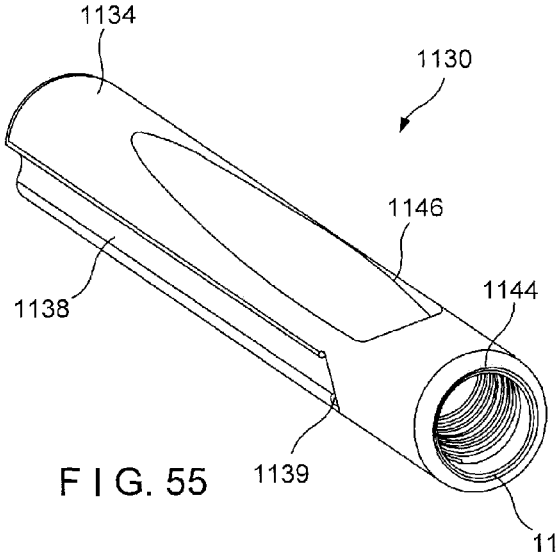

FIG. 55

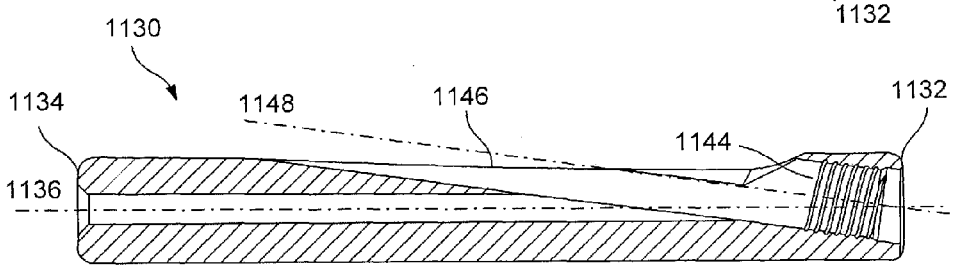

FIG. 56

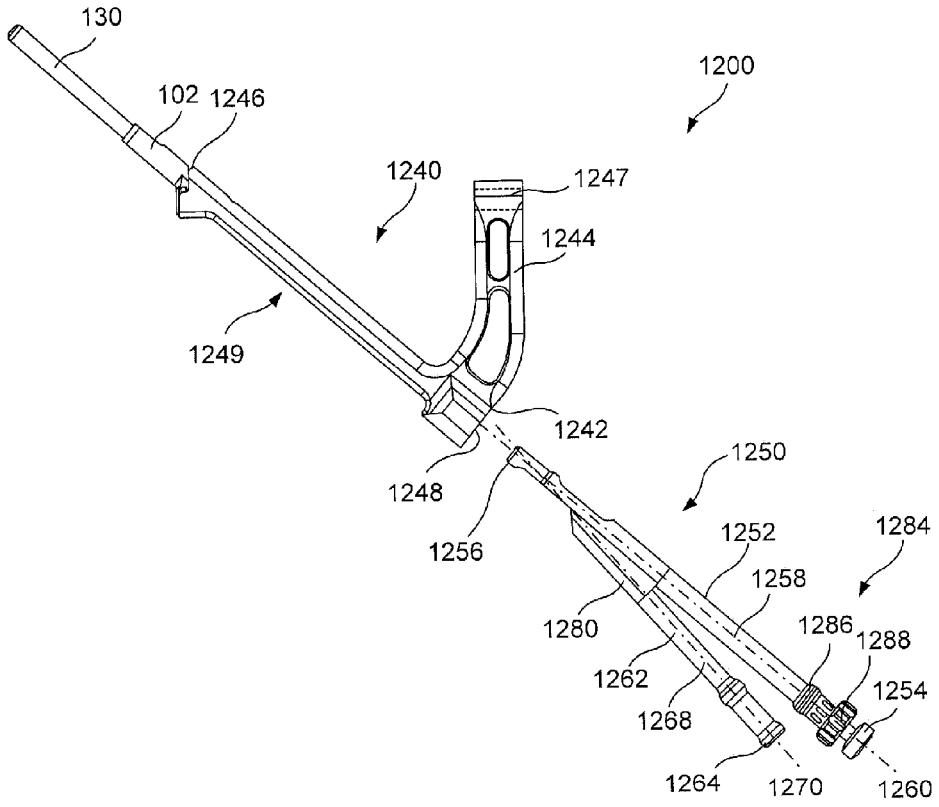
130
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FIG. 57

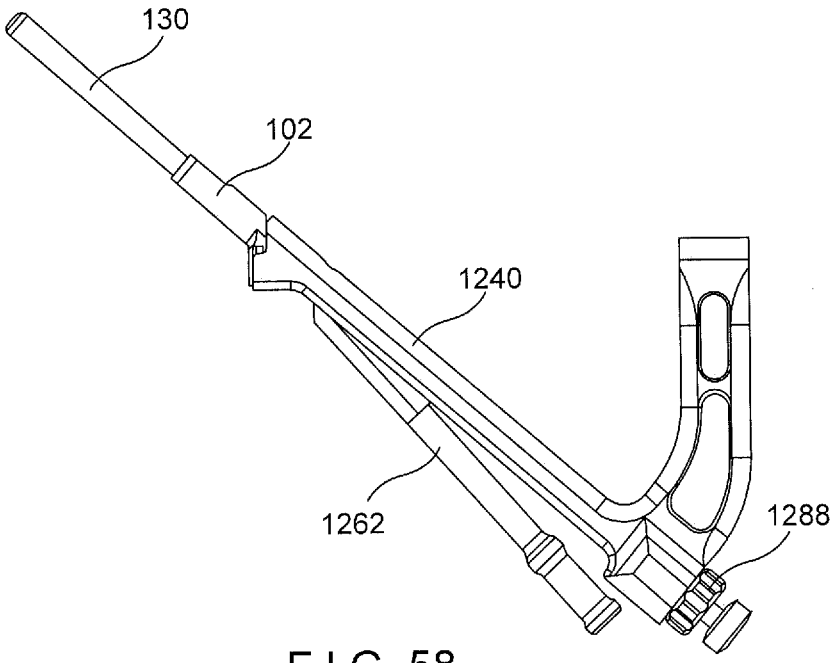


FIG. 58

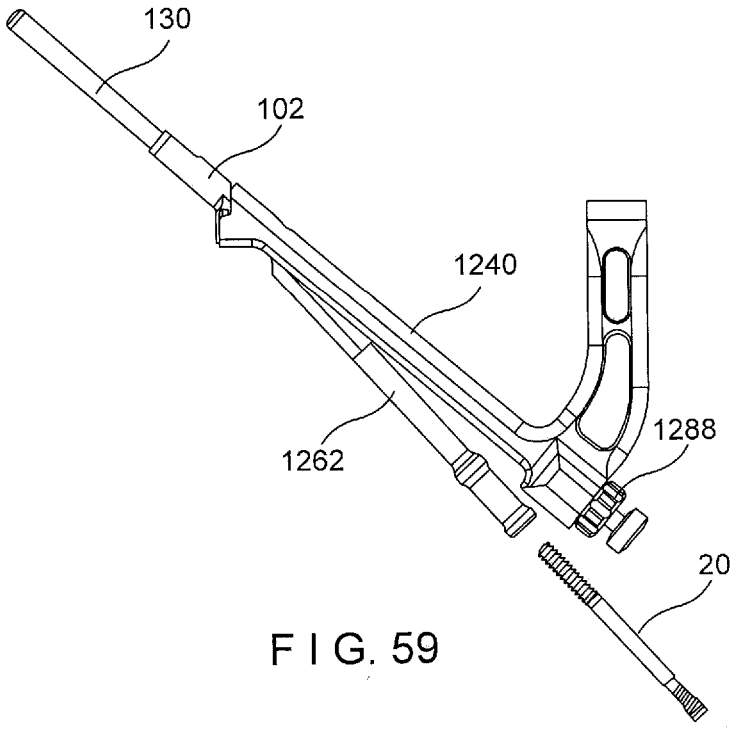
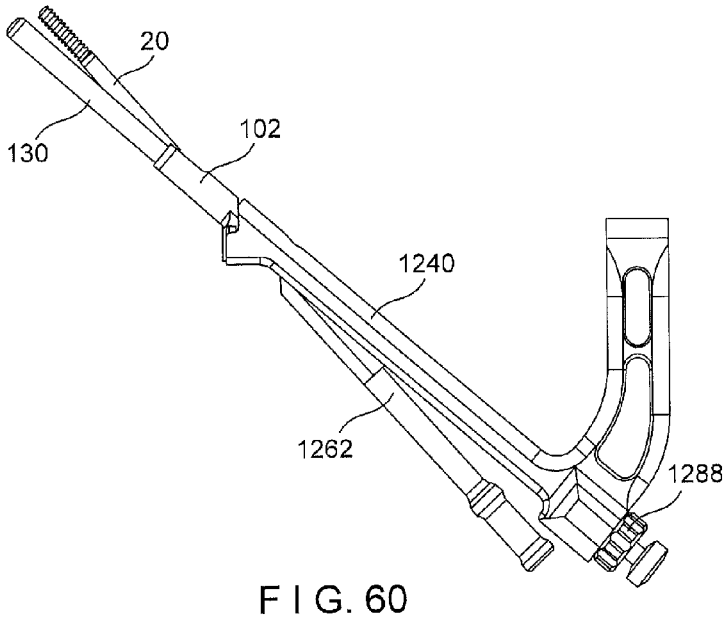
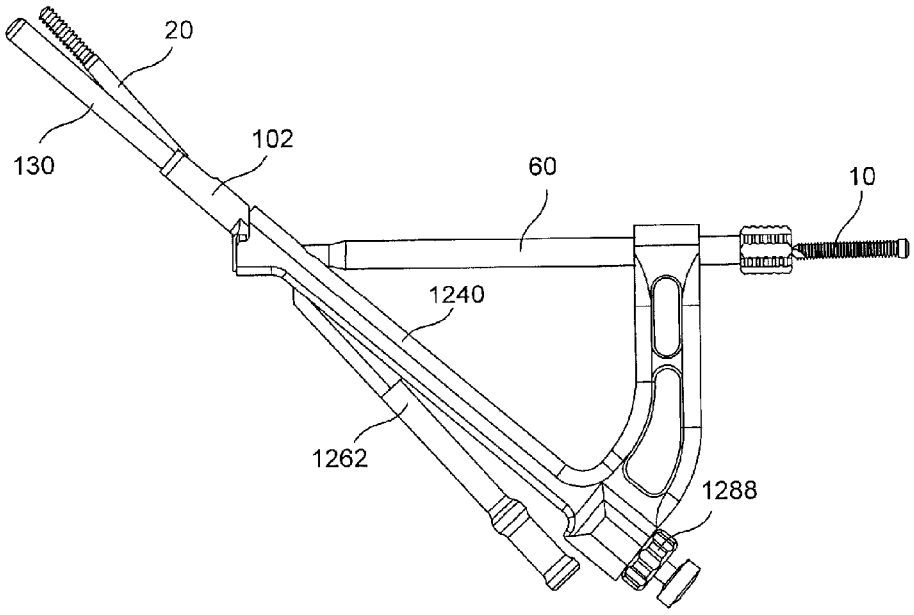


FIG. 59



F I G. 60



F I G. 61

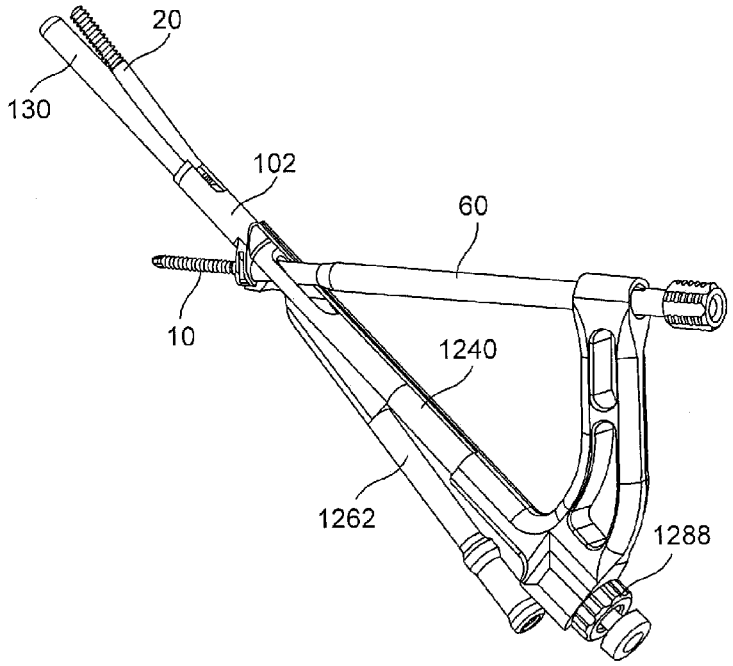


FIG. 62

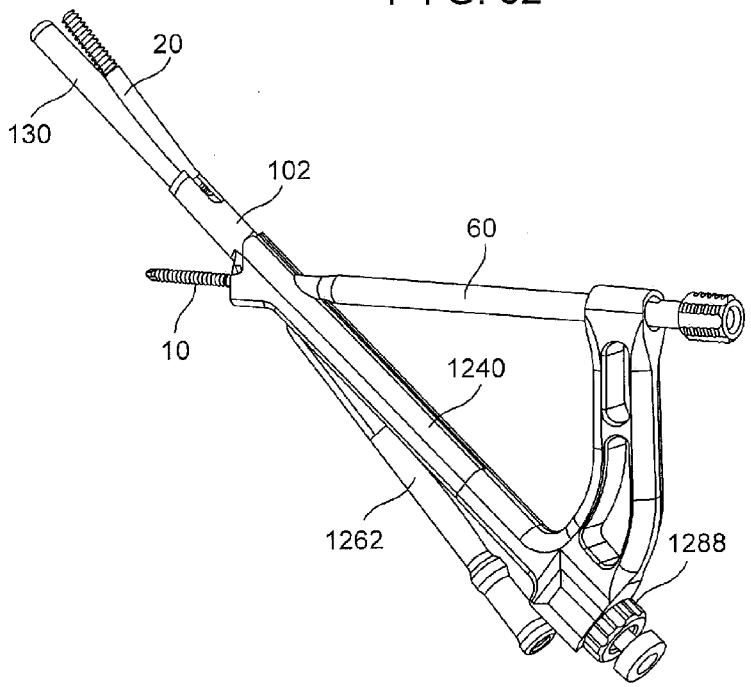


FIG. 63

FEMORAL NECK FRACTURE IMPLANT

PRIORITY CLAIM

This application is a National Phase application of PCT Patent Application Serial No. PCT/CN2012/001563 filed on Nov. 19, 2012 which claims priority to U.S. Provisional Application Ser. No. 61/561,439 entitled "Fastener" filed on Nov. 18, 2011, and U.S. Provisional Application Ser. No. 61/692,053 entitled "Femoral Neck fracture Implant" filed August 22. The entire specifications of the above-identified applications are expressly incorporated herein by reference.

FIELD OF THE INVENTION

The present invention generally relates to fasteners, fastener assemblies, kits for fastener assemblies, methods of assembling fastener assemblies, and methods of implanting fastener assemblies in a bone.

BACKGROUND

Femoral neck fractures are often treated with a pin or other implant inserted into the femoral head along an axis of the femoral neck. One such product is the Stryker® Hansson® Pin System, which is a rod first and second ends separated from one another by a side wall with no threading on its outer surface. The Hansson® Pin has a hook deployable from a first end region for fixing the Hansson® Pin in the femoral head. The hook is deployed by pushing a shaft in the second end, which in turns deploys the hook through a hole in the side wall. Generally, two or three Hansson® pins are inserted into the femoral head to fix the femoral head and to facilitate healing of the femoral neck fracture.

Other known products for treatment of femoral neck fractures include the Stryker® Gamma3® Hip Fracture system and the Smith+Nephew® Trigen® Intertan® Trochanteric Nail system. Both these systems include an intramedullary nail insertable into the femur and have rod-like fasteners insertable through the intramedullary nail into the femoral head for stabilizing the femoral neck fracture. Additionally, each of these systems includes a feature for minimizing unwanted rotation of the femoral head relative to the rod-like fastener, which is fixed in the nail. After the fastener is fixed, medial migration of the femoral head relative to the neck fracture may cause an end of the rod-like fastener to perforate the femoral head and damage the hip-joint. Another known product is the Synthes® DHS® which includes a bone plate fixable to the femur in the vicinity of the femoral head. The bone plate is prevented from rotating once positioned by a plurality of bone screws extending through the plate into the femur. The bone plate includes a channel extending across a portion positioned to permit a rod-like fastener to be passed through the channel into the femoral head to stabilize the femoral head and allow healing of a femoral neck fracture. The rod-like fastener is impacted to drive it into the femoral head.

It is an object of the present invention to provide an improved system for femoral neck fracture fixation.

SUMMARY OF THE INVENTION

The present invention is directed to a device for implanting a bone fixation system comprising an insertion instrument extending from a proximal end to a distal end, the distal end having an engagement portion for removably engaging a proximal end of a bone plate, the insertion instrument having an elongated channel extending therethrough to permit insertion of a first protection sleeve therethrough, wherein a longitudinal axis of the elongated channel is coaxial with a longitudinal axis of a first opening extending through the bone plate and a first protection sleeve insertable into the elongated channel and guiding insertion of an anti-rotation screw therethrough and through the bone plate, a longitudinal axis of the first protection sleeve being angled with respect to the longitudinal axis of the elongated channel.

In a first aspect, the present invention provides an aiming instrument to guide insertion of a bone fixation device into a bone, comprising an aiming arm including a first portion and a second portion, the first portion extending from a proximal end to a distal end and having an elongated channel extending therethrough, the distal end having an engagement portion removably engaging a proximal end of the bone fixation device, a side wall of the aiming arm including an elongated slot open to the elongated channel; and an elongated element removably insertable into the elongated channel, the elongated element having a first shaft portion and a second shaft portion, the first shaft portion being inserted into the elongated channel and lockingly engaging the aiming arm, the second shaft portion extending through the elongated slot and having an opening extending therethrough to guide insertion of an anti-rotation screw therethrough and into the bone fixation device.

In a second aspect, the present invention includes a method of implanting a bone fixation device into a bone, comprising: engaging a distal end of a guide assembly to a proximal end of a bone fixation device so that a first portion of the guide assembly having an elongated channel extending therethrough is coaxial with a longitudinal axis of the bone fixation device, wherein the first portion extending from a proximal end to a distal end; inserting an elongated shaft portion through the elongated channel, the elongated shaft portion including a first protection sleeve; inserting the bone fixation device into a shaft of the bone so that a first portion of the bone plate is positioned over an outer surface of the bone and a second portion of the bone plate is received within the bone; and inserting an anti-rotation screw through the first protection sleeve until a shaft of the anti-rotation screw extends out of the bone fixation device at an angle offset from the longitudinal axis of the bone fixation device.

BRIEF DESCRIPTION OF THE DRAWINGS

Several embodiments of the invention will be described in the following by way of example and with reference to the accompanying drawings in which:

FIG. **1** shows a first perspective view of a bone fastener assembly according to a first exemplary embodiment of the invention;

FIG. **2** shows a second perspective view of the bone fastener assembly of FIG. **1**;

FIG. **3** shows a first perspective view of a bone plate of the bone fastener assembly of FIG. **1**;

FIG. **4** shows a second perspective view of the bone plate of FIG. **3**;

FIG. **5** shows a third perspective view of the bone plate of FIG. **3**;

FIG. **6** shows a cross-sectional view of the bone plate of FIG. **3**;

FIG. **7** shows a first perspective view of an implant shaft of the bone fastener assembly of FIG. **1**;

FIG. **8** shows a second perspective view of the implant shaft of FIG. **7**;

FIG. **9** shows a cross-sectional view of the implant shaft of FIG. **7**;

FIG. **10** shows a partial cross-sectional view of the bone fastener assembly of Fig.;

FIG. **11** shows a first surgical step for use of the bone fastener assembly of FIG. **1**;

FIG. **12** shows a second surgical step for use of the bone fastener assembly of FIG. **1**;

FIG. **13** shows a third surgical step for use of the bone fastener assembly of FIG. **1**;

FIG. **14** shows a fourth surgical step for use of the bone fastener assembly of FIG. **1**;

FIG. **15** shows a fifth surgical step for use of the bone fastener assembly of FIG. **1**;

FIG. **16** shows a sixth surgical step for use of the bone fastener assembly of FIG. **1**;

FIG. **17** shows a seventh surgical step for use of the bone fastener assembly of FIG. **1**;

FIG. **18** shows an eighth surgical step for use of the bone fastener assembly of FIG. **1**;

FIG. **19** shows a ninth surgical step for use of the bone fastener assembly of FIG. **1**;

FIG. **20** shows a tenth surgical step for use of the bone fastener assembly of FIG. **1**;

FIG. **21** shows a side view of the bone fastener assembly of FIG. **1** in a first post-operative configuration;

FIG. **22** shows a cross-sectional view of the bone fastener assembly of FIG. **21**;

FIG. **23** shows a side view of the bone fastener assembly of FIG. **1** in a second post-operative configuration;

FIG. **24** shows a cross-sectional view of the bone fastener assembly of FIG. **23**;

FIG. **25** shows a side view of a bone fastener assembly according to a first alternate embodiment of the invention;

FIG. **26** shows a cross-sectional view of the bone fastener assembly of FIG. **25**;

FIG. **27** shows a side view of a bone fastener assembly according to a second alternate embodiment of the invention;

FIG. **28** shows a cross-sectional view of the bone fastener assembly of FIG. **27**;

FIG. **29** shows a perspective view of a bone fastener assembly according to a third alternate embodiment of the invention;

FIG. **30** shows a perspective view of a bone fastener assembly according to a fourth alternate embodiment of the invention;

FIG. **31** shows a perspective view of a bone fastener assembly according to a fifth embodiment of the invention;

FIG. **32** shows a first surgical step for use of the bone fastener assembly of FIG. **31**;

FIG. **33** shows a second surgical step for use of the bone fastener assembly of FIG. **31**;

FIG. **34** shows a first embodiment of a kit for packaging any of the bone fastener assemblies according to the invention;

FIG. **35** shows a second embodiment of a kit for insertion devices for use with the bone fastener according to the invention;

FIG. **36** shows a perspective view of a bone fastener assembly according to another embodiment of the invention;

FIG. **37** shows a first perspective view of a bone plate of the bone fastener assembly of FIG. **36**;

FIG. **38** shows a second perspective view of the bone plate of FIG. **36**;

FIG. **39** shows a cross-sectional view of the bone plate of FIG. **36**;

FIG. **40** shows a first perspective view of an implant shaft of the bone fastener assembly of FIG. **36**;

FIG. **41** shows a second perspective view of the implant shaft of FIG. **40**;

FIG. **42** shows a third perspective view of the implant shaft of FIG. **40**;

FIG. **43** shows a cross-sectional view of the implant shaft of FIG. **40**;

FIG. **44** shows a side view of the implant shaft of FIG. **40**;

FIG. **45** shows a perspective view of an anti-rotation screw of the bone fastener assembly of FIG. **37**;

FIG. **46** shows a first surgical step for use of the bone fastener assembly of FIG. **36**;

FIG. **47** shows a second surgical step for use of the bone fastener assembly of FIG. **36**;

FIG. **48** shows a third surgical step for use of the bone fastener assembly of FIG. **36**;

FIG. **49** shows a fourth surgical step for use of the bone fastener assembly of FIG. **36**;

FIG. **50** shows a fifth surgical step for use of the bone fastener assembly of FIG. **36**;

FIG. **51** shows a perspective view of a bone fastener assembly according to another embodiment of the invention;

FIG. **52** shows a side view of the bone fastener assembly of FIG. **51**;

FIG. **53** shows a perspective view of a bone fastener assembly according to another embodiment of the invention;

FIG. **54** shows a first perspective view of an implant shaft according to another embodiment of the invention;

FIG. **55** shows a second perspective view of the implant shaft of FIG. **54**;

FIG. **56** shows a cross-sectional view of the implant shaft of FIG. **54**;

FIG. **57** shows a perspective view of an insertion device for the implant according to the invention in a first operative configuration;

FIG. **58** shows a perspective view of the device of FIG. **57** in a second operative configuration;

FIG. **59** shows a perspective view of the device of FIG. **57** in a third operative configuration;

FIG. **60** shows a perspective view of the device of FIG. **57** in a fourth operative configuration;

FIG. **61** shows a perspective view of the device of FIG. **57** in a fifth operative configuration;

FIG. **62** shows a first perspective view of the device of FIG. **57** in a sixth operative configuration; and

FIG. **63** shows a second perspective view of the device of FIG. **57** in the sixth operative configuration.

DETAILED DESCRIPTION

The present invention may be further understood with reference to the following description and the appended drawings, wherein like elements are referred to with the same reference numerals. The present invention relates to the treatment of fractures and, in particular, to devices for fixing femoral neck fractures. Exemplary embodiments of the present invention describe a bone plate having first portion positionable against an outer surface of a fractured or otherwise damaged bone and a second portion partially inserted into the bone. A first bone screw hole extends through the first portion and a second bone screw hole extends through the second portion. The second portion further receives a bone fixation shaft sized and dimensioned to extend across a fractured portion of the femoral neck into the femoral head. The bone fixation shaft includes a transverse opening extending through a side wall thereof along a transverse opening axis

angled with respect to a bone fixation shaft axis such that a bone fixation element (e.g., a bone screw) inserted through the transverse opening extends away from the shaft into the bone to aid in fixation and compression of the fracture while also preventing rotation of the femoral head relative to the bone, as will be described in greater detail later on. It should be noted that the terms "proximal" and "distal" as used herein, refer to a direction toward (proximal) and away from (distal) a user of the device. In an exemplary embodiment, the system and method disclosed herein may be used for femoral neck fractures. It is noted that although the exemplary system and method are directed to a fixation of a femoral head fracture, the exemplary bone fixation system may be used in any other bone in the body without deviating from the scope of the invention.

The exemplary system and method according to the invention provide a minimally invasive surgical technique for treating femoral neck fractures using one or two incisions depending on soft-tissue thickness, as those skilled in the art will understand. Furthermore, since the bone plate and shaft implant of the invention are inserted into the body simultaneously, the exemplary system and method according to the invention may be more quickly and accurately positioned as compared to present systems. As will be described in greater detail below, the exemplary method according to the invention eliminates the need for impacting the bone fixation device to insert it into the bone. It should also be noted that the terms "medial" and "lateral" as used herein indicate a direction toward (medial) and away from (lateral) a midline of the body of a patient within which the bone fixation device is to be implanted. Furthermore, the terms "cranial" and "caudal" as used herein are intended to indicate a direction toward a head (cranial) and toward the feet (caudal) of the patient within which the bone fixation device is to be implanted.

As shown in FIGS. **1-10**, a bone fixation system **100** according to a first embodiment of the present invention comprises a bone plate **102** sized and shaped for placement on a target portion of femoral shaft opposite the femoral head (i.e., over a location through which an axis of the femoral neck passes). The bone plate **102** comprises a first portion **104** shaped to engage an outer surface of the target portion of the femur along a first portion axis parallel to an axis of the shaft of the femur and a second portion **106** extending away from the first portion along a second portion axis **120** angled with respect to the first plane at an angle selected so that, when the first portion **104** is positioned over the target portion of the femur, the second portion axis **120** extends along the axis of the femoral neck. In one exemplary embodiment, the first and second portions **104**, **106** are angled such that a bone contacting surface **107** of the first portion **104** encloses an angle α of approximately 130° relative to the second portion axis **120**, as shown in FIG. **10**. At this angle, the second portion axis **120** encloses an angle β of approximately 40° relative to a locking hole axis **110** of a locking hole **108** extending through the plate **102**. It is noted, however, that any other angle may be used as required to accommodate a patient's anatomy without deviating from the scope of the invention. For example, the angle β may be 45°. The locking hole axis **110** in this embodiment, extends substantially perpendicular to the first portion axis. However, those skilled in the art will understand that the orientation of the locking hole axis **110** may be varied as desired. The locking hole **108** includes a multi-faceted surface such as threading **112** to threadedly engage a corresponding threading on a shaft **12** of a bone fixation element **10** (e.g., a bone screw) inserted therethrough. The bone fixation element **10** may be a standard locking screw known in the art. A proximal portion of the locking hole **108** may include a non-threaded recess **114** to seat a head **14** of the bone fixation element **10** as would be understood by those skilled in the art. An outer surface of the first portion **104** may be substantially rounded such that the first portion **104** has a smooth outer profile preventing soft tissue irritation.

The second portion **106** is substantially cylindrical and extends from the first portion **104** to a distal end **116** along a length selected so that, when the first portion **104** is positioned over the target portion of the femur, the second portion **106** extends through the femoral neck to a desired position within the femoral head. A central elongated channel **118** extends through the second portion along the second portion axis **120**. An outer surface of the channel is substantially smooth with the exception of an abutment **122** adjacent the distal end **116**. The abutment **122** extends proximally into the channel **118** a predetermined distance and includes a proximal seat **124** and an elongated face **126**. As will be described in greater detail later on, the proximal seat **124** provides a stop for an implant shaft **130** while the face **126** prevents and/or minimizes a rotation of the shaft **130** relative to the bone plate **102**.

The bone fixation system **100** further comprises an implant shaft **130** for insertion through the plate **102** along the axis of the femoral neck and the second portion axis **120** into the femoral head. The shaft **130** is formed as a an elongated substantially cylindrical member extending from a proximal end **132** to a distal end **134** along a central longitudinal axis **136**. A diameter of the implant shaft in this embodiment is approximately 10 mm. However, other dimensions may be used to accommodate difference in patient anatomy without deviating from the scope of the invention. In an exemplary embodiment, the distal end **134** may be blunt to prevent the implant shaft **130** from cutting through the bone **1**. An outer surface of the implant shaft **130** comprises an elongated cutout **138** extending from the proximal end **132** to the distal end **134** and forming a flat surface configured to engage the face **126** of the abutment **122** preventing rotation of the shaft **130** relative to the plate **102**. As those skilled in the art will understand, a shape of the cutout **138** is selected so that, when implanted, forces tending to rotate the fractured femoral head relative to the femoral shaft are countered, resulting in the femoral head being kept in a desired stable alignment with the femoral shaft. That is, the cutout **138** eliminates the need for a friction fit between the implant shaft **130** and the second portion **106** to prevent a rotation of the implant shaft **130**. Any rotational force applied thereto is converted to an angled moment arm applied to the implant shaft. The cutout **138** is a portion of an outer surface of the implant shaft **130** milled or otherwise formed to define a substantially planar face which engages the face **126** in an operative configuration, as will be described in greater detail later on. A proximal end of the cutout **138** comprises a tab **140** extending radially therefrom by a distance selected to permit the tab **140** to engage the seat **124** preventing the implant shaft **130** from being inserted distally past the seat **124** defining a maximum extent by which the shaft **130** may be inserted into the bone. In an operative configuration, the implant shaft **130** engages the bone plate **102** via a form fit. As will be described in greater detail below with respect to the method of use, the form fit engagement permits lateral and medial telescoping migration of the implant shaft **130** relative to the bone plate **102** after implantation. This migration permits the implant shaft **130** to move laterally as the head of the bone moves to a corrected position during healing.

The implant shaft **130** comprises a first channel **142** extending longitudinally therethrough from the proximal end **132** to the distal end **134** in alignment with the central longi-

tudinal axis **136**. In an exemplary embodiment, the first channel **142** is dimensioned to receive a guide wire (e.g., a Kirschner wire) therethrough to guide insertion of the implant shaft **130** into the bone. The implant shaft **130** further comprises a substantially cylindrical second channel **144** extending therethrough along an axis **148** from the proximal end **132** to a distal opening **146** on a side wall of the implant shaft **130**. The axis **148** in this embodiment is angled at approximately 7.5° relative to the central longitudinal axis **136**. In another embodiment, the angle may be 5°, 6°, 8° or any other angle greater than 5°. In yet another embodiment, the angle may range between 0° and 5°. As shown in FIG. **8**, the distal opening **146** of the second channel **144** is circumferentially separated from the cutout. Due to the angular orientation of the second channel **144** relative to the implant shaft **130**, an opening of the second channel **144** at the distal opening **146** is substantially oval to permit a shaft **22** of an anti-rotation screw **20** inserted therethrough to exit therefrom. Specifically, the second channel **144** has a substantially circular cross-section. However, due to the second channel **144** exiting the implant shaft **130** at an oblique angle, as shown in FIGS. **7-9**, the distal opening **146** has an oval shape. The proximal end of the second channel **144** is formed with a threaded portion **150** to threadedly engage threading formed on the shaft **22** of the anti-rotation screw **20**. The threaded portion **150** may have a tapered diameter to engage a tapered diameter of a head **24** of the anti-rotation screw **20** the diameter of the threaded portion **150** being selected to prevent the head **24** from being inserted therepast.

FIGS. **11-20** depict an exemplary method of use of the bone fixation system **100**. In a first step, a patient is placed in a supine position on an operating table and the fractured bone **30** is provisionally brought into a corrected alignment via one or more of traction, abduction and internal rotation as would be understood by those skilled in the art. A straight lateral incision approximately 3-4 cm in length is made proximal to a tip of a greater trochanter. The iliotibial tract is then split lengthwise and the vastus lateralis muscle is detached dorsally from the intramuscular membrane. The proximal femoral shaft of a bone **1** is then exposed without retracting the periosteum. A guide wire is inserted through a center of the femoral head at a desired angle until a distal end of the guide wire extends into the subchondral bone, as those skilled in the art will understand. If desired one or more additional guide wires may be inserted into the femoral head as would be understood by those skilled in the art. A known reaming device (not shown) is then guided over the guide wire to ream a bore hole for the insertion of an implant according to the invention. The reamer is then removed from the bone **30** and the physician measures the appropriate implant length and selects an appropriately sized implant shaft **130**. The implant shaft **130** is then inserted through the channel **118** of the second portion **106** of the bone plate **102** until engagement of the tab **140** with the seat **126** prevents further distal movement of the implant shaft **130**. The assembled bone plate **102** and implant shaft **130** are then attached to an insertion instrument **40** including an arm portion **42** and an elongated shaft portion **44**, a distal end **46** of which removably grasps the bone plate **102**, as shown in FIGS. **11-13**. It is noted that although the arm portion **42** is depicted with a curvature, any other shape may be used without deviating from the scope of the invention. The arm portion **42** includes a first opening **48** extending through a first portion at a first end thereof and a second opening **50** extending through a second portion at a second end thereof. As will be described in greater detail below, the first opening **48** according to this embodiment, has a substantially circular cross-section to permit insertion of a substantially cylindrical first protection sleeve **60** therethrough. The second opening **50** has a substantially oblong (e.g., oval, rectangular, etc.) cross-sectional shape to permit insertion of a second protection sleeve **70** therethrough, as will also be described in greater detail below. In an exemplary embodiment, the bone plate **102** is slidably inserted into engagement with the distal end **46**, although other attachment mechanisms may be employed without deviating from the scope of the invention. The exemplary system **100** eliminates the need for an impactor to drive the bone plate **102** and implant shaft **130** into the bone. In an alternate embodiment, however, an impactor (not shown) may be used to first impact the implant shaft **130** into the femoral neck of a bone **1** and into the femoral head and subsequently impact the bone plate **102** into a lateral portion of the bone **1** until the plate **102** seats flush against the bone. Specifically, once the bone plate **102** has been attached to the insertion instrument **40**, an impactor may be inserted through the bone plate **102** against the implant shaft **130** to impact the system **100** into the bone. The impactor (not shown) and the guide wire (not shown) may then be removed from the bone, leaving the insertion instrument **40** and system **100** positioned in the bone, as shown in FIG. **14**.

A first protection sleeve **60** is then inserted through the first opening **48** in the insertion instrument **40**. The first protection sleeve **60** may extend through the first opening **48** and into the distal end **46** of the insertion instrument **40** at a predetermined angle relative to the angle of the elongated shaft portion **44**. In an exemplary embodiment, the first protection sleeve **60** and elongated shaft **44** enclose an angle of approximately 40°, although other angles may be used without deviating from the scope of the invention. The first protection sleeve **60** guides the drilling of a hole into the bone **1** to permit insertion of the bone fixation element **10** (i.e., a bicortical shaft screw) therein. Specifically, a drilling mechanism known in the art may be inserted through the first protection sleeve **60** to drill an opening through the locking hole **108** of the bone plate **102** and into the bone **1**. The drilling mechanism may then be removed and the bone fixation element **10** may be inserted through the first protection sleeve **60** and bone plate **102** and into the bone **1**. Dimensions of the bone fixation element **10** are selected to permit bicortical insertion thereof through the bone **1**, as those skilled in the art will understand. The first protection sleeve **60** may then be removed from the insertion instrument, leaving the bone fixation element **10** in place within the bone **1**.

As shown in FIGS. **17-18**, the second protection sleeve **70** may comprise a first elongated shaft portion **72** having a first channel **74** extending therethrough, the first elongated shaft portion **72** being insertable through the insertion instrument. In an operative configuration, a longitudinal axis **75** of the first channel **74** is substantially aligned with the longitudinal axis **136** of the implant shaft **130**. The second protection sleeve **70** further comprises a second elongated shaft portion **76** having a second channel **78** extending therethrough, a longitudinal axis **77** of the second elongated shaft portion **76** being offset from the longitudinal axis **75** by approximately 5° to align with the axis **148** of the implant shaft **130**, as described in greater detail earlier and depicted in FIG. **9**. The elongated shaft **44** may comprise an elongated slot (not shown) on a side wall thereof to permit insertion of second protection sleeve **70** to the position depicted in FIG. **18**.

Once the second protection sleeve **70** has been seated against the proximal end **132** of the implant shaft **130**, a drilling mechanism (not shown) may be inserted through the second channels **78** and **144** to prepare the bone **1** for the anti-rotation bone screw **20**. As those skilled in the art will understand, in softer bone, pre-drilling may not be necessary.

As would be understood by those skilled in the art, a driving mechanism (not shown) may then be used to insert the anti-rotation screw **20** through the second protection sleeve **70** and implant shaft **130** and into the bone **1**. The second protection sleeve **70** and insertion instrument **40** may then be removed from the body, leaving the system **100** implanted in the bone **1**. Once implanted, the head of the femur is prevented from rotation relative to the bone **1** via the anti-rotation screw **20** and bone plate **102**. The shaft **130** is permitted to migrate within a desired range relative to the bone plate **102**. Specifically, the combined implant shaft **130** and bone fixation element anti-rotation screw **20** inserted therethrough are capable of migrating a distance x from the configuration of FIGS. **21-22** to the configuration of FIGS. **23-24**. Those skilled in the art will understand that this migration of the implant shaft **130** relative to the bone plate **102** minimizes the risk of medial perforation of the implant shaft **130** through the femoral head after implantation and as the bone heals.

It is noted that although the exemplary method depicts the insertion of the bicortical screw **10** first, followed by the insertion of the anti-rotation screw **20**, the order of insertion may be changed without deviating from the scope of the invention to suit, for example, a surgeon's preference. For example, the method of insertion for the system **800** as described below is directed to the insertion of an anti-rotation screw first, followed by a bi-cortical screw.

FIGS. **25-26** depict a system **200** according to a first alternate embodiment according to the invention. The system **200** is formed substantially similarly to the system **100**, wherein like elements have been referenced with like reference numerals. The system **200** comprises a bone plate **102** and an implant shaft **230**. The implant shaft **230** is formed substantially similarly to the implant shaft **130** with the exception of a reduced diameter distal portion **240**. The implant shaft **230** extends from the proximal end **132** to the distal end **234**. The reduced diameter distal portion **240** extends proximally from the distal end **134** a predetermined distance. As those skilled in the art will understand, the reduced diameter portion **240** reduces the amount of bone removal needed for insertion of the implant shaft **230** into the bone and has a wider spread between the distal end **234** of the implant shaft **230** and distal end of the anti-rotation screw **20**.

FIGS. **27-28** depict a system **300** according to a second alternate embodiment according to the invention. The system **300** is formed substantially similarly to the system **100**, wherein like elements have been referenced with like reference numerals. The system **300** comprises a bone plate **102** and an implant shaft **330** formed substantially similarly to the implant shaft **130** with the exception of a threaded distal portion **340**. The implant shaft **330** extends from a proximal end **132** to a distal end **234** with the threaded distal portion **340** extending proximally from the distal end **134** a predetermined distance. As those skilled in the art will understand, the threaded distal portion **340** aids in retention of the implant shaft **330** within the bone **1**.

FIG. **29** depicts a system **400** according to a third alternate embodiment according to the invention. The system **400** is formed substantially similarly to the system **100**, wherein like elements have been referenced with like reference numerals. The system **400** comprises a bone plate **102** and an implant shaft **430**. The implant shaft **430** is formed substantially similarly to the implant shaft **130** with the exception of a position and angle of a channel **444** extending therethrough. Specifically, the channel **144** of the system **100** extends from the proximal end **132** to a distal opening **146** positioned on a cranial surface of the implant shaft in an operative configuration. In contrast, the channel **444** extends from the proximal end **132** to a distal end **446** positioned on a caudal surface of the implant shaft **430** in an operative configuration. A channel axis **448** of the channel **444** is angled at approximately −5° relative to the central longitudinal axis **136**. However, those skilled in the art will understand that this angle may vary as desired without departing from the scope of the invention.

FIG. **30** depicts a system **500** according to a fourth alternate embodiment according to the invention. The system **500** is formed substantially similarly to the system **100**, wherein like elements have been referenced with like reference numerals. The system **500** comprises a bone plate **102** and an implant shaft **530** formed substantially similarly to the implant shaft **130** with the exception of a position and angle of a channel **544** extending therethrough. Specifically, the channel **544** extends from the proximal end **132** to a distal end **546** positioned on a surface of the implant shaft **530** which, in an operative configuration, faces one of an anterior and a posterior direction. A physician may determine which of the systems **100**, **400** and **500** to use in accordance with, for example, a size and location of a fracture in the bone, as those skilled in the art will understand.

FIGS. **31-33** depict a system **600** according to a fifth alternate embodiment according to the invention. The system **600** is formed substantially similarly to the system **100**, wherein like elements have been referenced with like reference numerals. The system **600** comprises a bone plate **602** and the implant shaft **130**, bone plate **602** being formed substantially similarly to the implant shaft **130** with the exception of an additional locking hole extending therethrough. Specifically, the bone plate **602** comprises a central longitudinal channel **118**. A first locking hole **608** is positioned caudally of the central longitudinal channel **118** and is substantially similar to the locking hole **108**. A second locking hole **609** extends through the bone plate **602** cranially of the central longitudinal channel **118**. A hole axis **610** of the second locking hole is substantially parallel to the channel axis **120** of the central longitudinal channel **118** such that a bone fixation element **10'** inserted therethrough does not intersect any other portion of the system **600**.

An exemplary insertion method for the system **600** is substantially similar to the method disclosed earlier with respect to system **100**. However, once the first and second bone fixation elements **10**, **20** have been inserted, a third drill sleeve **80** is inserted through the insertion instrument **40** to align with the second locking hole. A drilling mechanism (not shown) is inserted through the drill sleeve **80** and into the bone to define the trajectory of the bone fixation element **10'**. A driving mechanism (not shown) is then inserted through the drill sleeve **80** to screw the bone fixation element **10'** into the bone **1**. The exemplary system **600** provides added structural support to the bone **1** and may be particularly advantageous in bones with multiple fractures or otherwise weaker bones.

As shown in FIG. **34**, the systems **100**, **200**, **300**, **400**, **500** and **600** may be manufactured and packaged as a kit **700** including the bone plate **102**, **602**, implant shaft **130**, **230**, **330**, **430**, **530**, and anti-rotation screw **20** along with instructions for implantation as described above. The implant shaft **130**, **230**, **330**, **430**, **530** and anti-rotation screw **20** may be provided in corresponding dimensions to one another. The kit may be sold in various implant shaft lengths to suit the requirements of a particular procedure. The bone fixation element **10** may be offered separately. The kit **700** may include a molded packaging **702** formed of plastic or another suitable material having a removable seal **704** provided thereover, the seal **704** maintaining the sterility of the system.

FIG. **35** depicts a single-use kit for the instruments required for the completion of a bone fixation procedure according to

the invention, as described above with respect to the exemplary method of use for the system **100**. A kit **750** according to the invention may include the insertion instrument **40**, the corresponding removable shaft portion **44** and the first and second protection sleeves **60**, **70**. In an operative configuration, the removable shaft portion **44** is attached to an elongated shaft **46**, which is further attached to the second protection sleeve **70** via a Y-connector. A side wall of the insertion instrument **40** includes a slot (not shown) permitting insertion of the Y-connector therepast. The removable shaft portion **44** further comprises a tab **48** including a protruding distal end **49** extending radially away therefrom. In an operative configuration, the tab **48** is received through the second opening **50** with a snap-fit engagement. Specifically, the tab **48** is deformed radially inward when being inserted through the second opening **50**. Once moved thereinto, the tab **48** moves radially outward to assume its initial configuration so that the protruding distal end **49** is received within a corresponding portion of the second opening **50**, thus locking the shaft portion **44** to the instrument **40**. The insertion instrument **40** may be made of a low-cost plastic injection molding while the protection sleeves **60**, **70** and shaft portion **44** may be formed of a low-cost metal injection molding. In another embodiment, the insertion instrument **40** may be made of standard parts (e.g., standard tubing, etc.) connected to form the depicted structure. The kit **750** may be sold as a single unit for use with any of the exemplary systems **100**, **200**, **300**, **400**, **500**, **600**, **800** disclosed herein.

FIGS. **36-50** depict a system **800** according to another alternate embodiment according to the invention. The system **800** is formed substantially similarly to the system **100**, wherein like elements have been referenced with like reference numerals. The system **800** comprises a bone plate **802** and an implant shaft **830**. The implant shaft **830** is formed substantially similarly to the implant shaft **130** with the exception of the structural differences noted below.

The bone plate **802** comprises a first portion **804** shaped to engage an outer surface of the target portion of the femur along a first portion axis parallel to an axis of the shaft of the femur and a second portion **806** extending away from the first portion along a second portion axis angled with respect to the first plane at an angle selected so that, when the first portion is positioned over the target portion of the femur, an axis of the second portion extends along the axis of the femoral neck. The first portion **804** comprises a locking hole **808** extending through the plate **802** along a locking hole axis **810** which extends substantially perpendicular to a first portion axis. The locking hole **808** is formed substantially similar to the locking hole **108** of the system **100** and may include a multi-faceted surface such as threading **812** to threadedly engage a corresponding threading on the shaft **12** of the bone fixation element **10** (e.g., a bone screw) inserted therethrough. An outer surface of the first portion **804** is substantially rounded such that the first portion **804** has a smooth outer profile substantially matching that of the target portion of the femur. The outer surface of the first portion **804** further comprises one or more recesses **805** configured and dimensioned to permit grasping of the bone plate **802** by the insertion instrument **40**, as will be described in greater detail with respect to the exemplary method below. The recess **805** may extend substantially parallel to an axis of the first portion **804**. In an exemplary embodiment, first and second recesses **805** may be provided on opposing walls of the first portion **804** to permit grasping of the bone plate **802**. Dimensions of each of the recesses may be selected to conform to the dimensions of a gripping portion of the implant holder

The second portion **806** is substantially cylindrical and extends from the first portion **804** to a distal end **816**. A central elongated channel **818** extends through the second portion along a second portion axis **820**. An outer surface of the channel **818** is substantially smooth with the exception of an abutment **822** adjacent the distal end **816**. The abutment **822** extends radially into the channel **818** a predetermined distance and is bordered on both sides by grooves **824**. A cutout **826** extends proximally from the distal end **816** of the second portion. In an exemplary embodiment, the cutout **826** is substantially rectangular with rounded corners and is open to the distal end **816**. The cutout **826** is positioned so that, in an operative configuration, the cutout faces a cranial direction. Dimensions of the cutout **826** may be selected to permit the anti-rotation screw **80** to extend therefrom, as shown in FIGS. **35** and **45-46**. That is, the cutout **826** prevents the need for advancement of the implant shaft **830** out of the bone plate **102** beyond a threshold distance. Rather, in smaller bones, the implant shaft **830** may extend out of the bone plate **802** by only a minimal required distance, with a distal end **846** of the second channel **844** be housed within the second portion **806**. In an operative configuration, the anti-rotation screw **80** may be inserted through the implant shaft **830** to extend out of the cutout **826**. As those skilled in the art will understand, the cutout **826** may be formed with any length to permit use of the system **800** in bones having varying dimensions. Furthermore, for use in longer bones, the cutout **826** may optionally be omitted. Furthermore, the cutout **826** allows telescoping of the implant shaft **830** relative to the bone plate **802**.

The second portion **806** further comprises first and second recesses **828** provided on opposing walls adjacent a proximal end of the channel **818**. The first and second recesses are configured and dimensioned to permit insertion of a corresponding portion of a locking core therethrough to guide insertion of the bone plate **802** over the bone, as will be described in greater detail below.

The implant shaft **830** is formed as a an elongated substantially cylindrical member extending from a proximal end **832** to a substantially blunt distal end **834** along a central longitudinal axis **836**. An outer surface of the implant shaft **830** comprises an elongated cutout **838** extending from a proximal end **839** to the distal end **834**, the cutout **838** have a shape corresponding to the shape of the abutment **822** and grooves **824** to permit engagement therewith. As described in greater detail with respect to the system **100**, this engagement prevents rotation of the shaft **830** relative to the plate **802**. As those skilled in the art will understand, engagement of the abutment **822** with the proximal end **839** of the cutout **838** prevents the shaft **130** from extending distally out of the plate **802**, defining a maximum extent by which the shaft **830** may be inserted into the bone. Furthermore, due to the hemispherical shape of the cutout **838**, a rotational force applied to the implant shaft **830** after implantation is converted to a substantially perpendicular moment arm, preventing wedging of the implant shaft **830** against walls of the second portion **806**. The prevention of the wedging of the implant shaft **830** also prevents high-friction forces that may influence the ability of the implant shaft **830** to telescope relative to the plate **802**.

The implant shaft **830** comprises a first channel **842** extending longitudinally therethrough from the proximal end **832** to the distal end **834** in alignment with a central longitudinal axis **836**. The first channel **842** is dimensioned to receive a guide wire (e.g., a Kirschner wire) therethrough to guide insertion of the implant shaft **830** into the bone. The implant shaft **830** further comprises a second channel **844** extending therethrough along an axis **848** from the proximal end **132** to a distal opening **846** on a side wall of the implant shaft **830**,

the distal opening **846** being circumferentially separated from the cutout **838**. The distal opening **846** is substantially oval to permit a shaft **82** of an anti-rotation screw **80** inserted therethrough to exit therefrom. Similar to the distal opening **146**, the distal opening **846** is oval due to an oblique position of the substantially circular second channel **844** relative to the implant shaft **830**. The proximal end of the second channel **844** includes threading **850** to threadedly engage threading formed on the shaft **82** of the anti-rotation screw **80**, as will be described in greater detail below. Whereas the threading **150** of the implant shaft **130** is substantially tapered, the threading **850** is substantially cylindrical.

The anti-rotation screw **80** extends from a head **84** at a proximal end and along the shaft **82** to a distal end **86**. The shaft **82** includes a first portion **88** having a first outer diameter selected to permit engagement with the threading **850** of the implant shaft **830**. Specifically, the first portion **88** includes a first threaded region **89** including a double-lead thread to aid in engagement thereof with the threading **850**. The first portion **88** also includes a non-threaded tapered region **90** shaped to allow telescoping of the anti-rotation screw **80** when inserted into a target orientation in the bone. The first portion **88** preferably has a substantially tapered shape corresponding to a tapered shape of the second channel **844**. A second non-threaded portion **92** extends distally from the first portion **88**. A diameter of the second portion **92** is greater than a diameter of the tapered region **90**, forming a telescoping stop **94** at a junction thereof. In an operative configuration, the second portion **92** extends out of the implant shaft **830** and into the bone. A third threaded portion **96** extends distally from the second non-threaded portion **94** and includes single lead spongiosa threading configured to engage bone in an operative configuration, as will be described in greater detail with respect to the exemplary method below. As those skilled in the art will understand, the double-lead thread of the first threaded region **89** matches a pitch of the single-lead thread of the third portion **96**. In another embodiment, a higher pitch of the thread in the third threaded portion **96** can be used to facilitate compression of the femoral head onto the shaft **82**.

An exemplary method of use of the bone fixation system **800** is substantially similar to the method of use of the system **100** described in detail earlier with respect to FIGS. **11-20**. Specifically, once the fractured bone **30** has been provisionally brought into a corrected alignment and an incision has been made, one or more guide wire are inserted into a center of the femoral head at a desired angle until a distal end of the guide wire extends into the subchondral bone, as those skilled in the art will understand. A known reaming device (not shown) is then guided over the guide wire to ream a bore hole for the insertion of an implant according to the invention. The implant shaft **830** is then inserted through the channel **818** of the second portion **806** of the bone plate **802** until engagement of the abutment **822** with the proximal end **839** of the cutout **838** prevents further distal movement of the implant shaft **830**. The assembled bone plate **802** and implant shaft **830** are then attached to the insertion instrument **40** including an arm portion **42** and an elongated shaft portion **44**, a distal end **46** of which removably grasps the recesses **805** of the bone plate **802**. Once the bone plate **802** has been attached to the insertion instrument **40**, an impactor may be inserted through the bone plate **802** and implant shaft **830** to impact the system **800** into the bone. The impactor (not shown) and the guide wire (not shown) may then be removed from the bone, leaving the insertion instrument **40** and system **800** positioned in the bone.

As shown in FIGS. **48-49**, the second protection sleeve **70** is then inserted through the second opening **50** and through the elongated shaft **44** until a distal end thereof is seated against the implant shaft **830**. A drilling mechanism (not shown) may be inserted through the second channels **78** and **844** to prepare the bone **1** for the anti-rotation bone screw **80**. As those skilled in the art will understand, in softer bone, pre-drilling may not be necessary. As would be understood by those skilled in the art, a driving mechanism (not shown) may then be used to insert the anti-rotation screw **80** through the second protection sleeve **70** and implant shaft **830** and into the bone **1**. The second protection sleeve **70** and insertion instrument **40** may then be removed from the body, leaving the system **800** implanted in the bone **1**. Once implanted, the head of the femur is prevented from rotation relative to the bone **1** via the anti-rotation screw **80** and bone plate **802**.

As shown in FIG. **50**, the first protection sleeve **60** is then inserted through the first opening **48** in the insertion instrument **40** to guide the drilling of a hole into the bone **1** to permit insertion of the bone fixation element **10** (i.e., a bicortical shaft screw) therein. Specifically, a drilling mechanism known in the art may be inserted through the first protection sleeve **60** to drill an opening through the locking hole **808** of the bone plate **802** and into the bone **1**. The drilling mechanism may then be removed and the bone fixation element **10** may be inserted through the first protection sleeve **60** and bone plate **802** and into the bone **1**.

FIGS. **51-52** depict a system **900** according to yet another embodiment of the invention. The system **900** is formed substantially similarly to the system **800** and includes a bone plate **902** having first and second portions **904**, **906** and an implant shaft **930** with one or more elastic deflecting structures at a distal end thereof. The implant shaft **930** includes an elongated channel **942** extending therethrough from a proximal end (not shown) to a distal end **934**. A second channel **944** extends therethrough at an angle relative to a central longitudinal axis thereof to house the anti-rotation screw **80**, as described in greater detail with respect to earlier embodiments. The implant shaft **930** further comprises a plurality of elongated slots **950** extending proximally from the distal end **934** and terminating at a substantially circular cutout at proximal ends **952**. In an exemplary embodiment, the implant shaft **930** may include two slots **950** provided on opposing walls of the implant shaft **930** to define two compliant arms **954**. It is noted however, that any number of slots **950** may be provided without deviating from the scope of the invention. As those skilled in the art will understand, the compliant arms **954** increase an overall elasticity of the implant shaft **930** by distributing a peak load applied to the distal end **934**, permitting the shaft **930** to deform instead of fracturing when subjected to excessive loads. By allowing for deformation of the implant shaft **930**, the compliant arms **954** prevent inadvertent penetration of the implant shaft **930** through the bone, as those skilled in the art will understand.

FIG. **53** depicts a system **1000** according to another embodiment of the invention. The system **1000** depicts an implant shaft **1030** formed substantially similar to the implant shafts **130**, **830** described above. However, instead of being inserted through a bone plate, the implant shaft **1030** is insertable through an intramedullary nail **1002**. The intramedullary nail **1002** includes a transverse opening **1004** extending therethrough, the transverse opening **1004** having a shape formed by first and second overlapping circular channels **1006**, **1008**. The first circular channel **1006** is configured to permit insertion of the implant shaft **1030** therethrough and extends through the intramedullary nail **1002** at a first angle. The second circular channel **1008** is open to the first circular

channel and extends through the intramedullary nail **1002** at a second angle different than the first angle. Specifically, an angle of the second circular channel **1008** substantially matches an angle of the second channel **144** relative to the first channel **142** of the implant shaft **1030**. Thus, the anti-rotation screw **80** inserted through the second channel **144** is guided through the second channel **1008** and out of an opposing wall of the intramedullary nail **1002**.

An outer wall of the implant shaft **1030** may include a cutout **1038** configured to engage a respectively shaped abutment (not shown) provided in the first channel **1006**. Engagement of the abutment (not shown) with the cutout **1038** prevents rotation of the implant shaft **1030** relative to the transverse opening **1004**. Furthermore, engagement of the abutment (not shown) with a proximal end **1039** of the cutout **1038** limits a depth of insertion of the implant shaft **1030** into the bone, as described in greater detail in earlier embodiments.

FIGS. **54-56** depict an implant shaft **1130** according to yet another embodiment according to the invention. The implant shaft **1130** is formed substantially similarly to the implant shafts **130**, **830** except as noted hereinafter. The implant shaft **1130** may be used with any of the bone plates **102**, **602**, **802**, **902** and intramedullary nails **1002** disclosed above. The implant shaft **1130** is formed as an elongated substantially cylindrical member extending from a proximal end **1132** to a substantially blunt distal end **1134** along a central longitudinal axis **1136**. An outer surface of the implant shaft **1130** comprises an elongated cutout **1138** extending from a proximal end **1139** to the distal end **1134**, the cutout **1138** being formed substantially similar to the cutout **838**. However, unlike earlier embodiments, the implant shaft **1130** does not comprise a central longitudinal channel extending therethrough. Rather, the implant shaft **1130** comprises only a channel **1144** extending therethrough along an axis **1148** from the proximal end **1132** to a distal opening **1146** on a side wall of the implant shaft **1130** to receive, for example, an anti-rotation screw (not shown) therethrough. Accordingly, unlike earlier embodiments, which may optionally be guided over a pre-positioned guide wire into the bone, the exemplary implant shaft **1130** may be inserted into the bone after removal of the guide wire therefrom. That is, the implant shaft **1130** may be guided into the bone via a hole pre-drilled therein.

Although the invention and its advantages have been described in detail, it should be understood that various changes, substitutions, and alterations can be made herein without departing from the spirit and scope of the invention as defined by the appended claims. For example, any of the implant shafts and bone plates disclosed herein may optionally be coated with Diamond-Like Carbon (DLC) to prevent osseointegration thereof, as those skilled in the art will understand and/or to reduce friction and therefore improve telescoping between the bone plate and the implant shaft. Moreover, the scope of the present application is not intended to be limited to the particular embodiments of the process, machine, manufacture, composition of matter, means, methods and steps described in the specification. As one of ordinary skill in the art will readily appreciate from the disclosure of the present invention, processes, machines, manufacture, composition of matter, means, methods, or steps, presently existing or later to be developed that perform substantially the same function or achieve substantially the same result as the corresponding embodiments described herein may be utilized according to the present invention.

FIGS. **57-62** depict a kit **1200** according to another embodiment of the invention as required for the completion of a bone fixation procedure. The kit **1200** is formed substantially similarly to the kit **750** described earlier, with like elements being referenced with like reference numerals. However, whereas the kit **750** is configured for single-use, the kit **1200** may be used any number of times to perform multiple procedure. It is noted that the kit **1200** may also be configured for single-use without deviating from the scope of the invention. Furthermore, whereas the removable shaft portion **44** of the kit **750** engages the instrument **40** with a click/snap-fit engagement, a removable shaft portion **1250** of the kit **1200** engages an instrument **1240** with a threaded engagement, as will be described in greater detail hereinafter. It is noted, however, that the kit **1200** may also employ the snap-fit engagement of kit **750** without deviating from the scope of the invention. The kit **1200** according to the invention includes an insertion instrument **1240** extending from a proximal end **1242** including a curved arm **1244** to a distal end **1246**. A first opening **1247** extends through the arm **1244** to guide the first protection sleeve **60** therethrough, as will be described in greater detail with respect to the exemplary method below. A second opening **1248** extends into the proximal end **1242** permitting insertion of the removable shaft portion **1250** thereinto. The instrument **1240** also comprises an elongated slot **1249** on a side wall thereof to accommodate the width of the shaft portion **1250** when inserted therein.

The removable shaft portion **1250** includes a first elongated shaft portion **1252** extending from a first proximal end **1254** to a distal end **1256** and including a first channel **1258** extending therethrough. In an operative configuration, a longitudinal axis **1260** of the first channel **1258** is substantially aligned with the longitudinal axis **136** of the implant shaft **130**. The removable shaft portion **1250** further comprises a second elongated shaft portion **1262** formed substantially similarly to the second protection sleeve **70** and extending from a second proximal end **1264** to the distal end **1256**. A second channel **1268** extends through the second shaft portion **1262** along a longitudinal axis **1270** offset from the longitudinal axis **1260** by approximately 7.5° to align with the axis **148** of the implant shaft **130**, as described in greater detail with respect to earlier embodiments. The first and second elongated shaft portions **1252**, **1262** extend to a common distal end **1256** via a connecting element **1280**. The connecting element **1280** according to this embodiment comprises an elongated slot **1282** extending through a side wall thereof to permit insertion of the anti-rotation screw **20** therethrough and through the implant **130** to extend into the bone, as will be described in greater detail with respect to the exemplary method below.

The first elongated shaft portion **1252** includes a locking element **1284** at the first proximal end **1254**. The locking element **1284** includes a threaded portion **1286** and a screw **1288** which may be rotated (e.g., manually by a user) to screw the threaded portion **1286** into a corresponding threaded region (not shown) provided within the opening **1248** of the instrument **1240**. Specifically, rotation of the screw **1288** rotates the entire first elongated shaft portion **1252** relative to the connecting element **1280**. In one embodiment of the invention, the first elongated shaft portion **1252** is removably attached to the connecting element **1280**. In another embodiment, the first elongated shaft portion **1252** is permanently attached to the connecting element **1280** and axially movable relative thereto within a predetermined range of motion corresponding to an axial length of the threaded portion **1286** to permit screwing and unscrewing thereof into the instrument **1240**, as those skilled in the art will understand. The second elongated shaft portion **1262** may also be either permanently

or removably attached to the connecting element **1280** as those skilled in the art will understand.

In accordance with an exemplary method according to the invention, a patient is placed in a supine position on an operating table and a fractured femur is provisionally brought into a corrected alignment via one or more of traction, abduction and internal rotation as would be understood by those skilled in the art. An incision is formed in the skin and the bone is reamed to create a bore hole for the insertion of an implant according to the invention. The assembled bone plate **102** and implant shaft **130** are then attached to the insertion instrument **1240** via a sliding engagement between the distal end **1246** and a proximal end of the bone plate **102**, as described in greater detail in earlier embodiments. The removable shaft portion **1250** is then inserted into the opening **1248** such that the distal end **1256** extends adjacent to the distal end **1246** of the instrument **1240**, as shown in FIG. **58**. The screw **1288** is then rotated to threadedly drive the first elongated shaft portion **1252** into the instrument **1240** and into threaded engagement with a threaded portion (not shown) of the opening **1248**. The locking element **1284** is configured so that, when the screw **1288** comes into contact with an outer surface of the instrument **1240**, the first elongated shaft portion **1252** is locked against rotation or axial movement relative to the instrument **1240**.

Once the shaft portion **1250** has been locked to the instrument **1240**, and the bone fixation system **100** inserted into the bone, a drilling mechanism (not shown) may be inserted through the channel **1270** to prepare the bone for the anti-rotation bone screw **20**. As those skilled in the art will understand, in softer bone, pre-drilling may not be necessary. A driving mechanism (not shown) may then be used to insert the anti-rotation screw **20** through the second elongated shaft portion **1262** and implant shaft **130** and into the bone, as shown in FIGS. **59** and **60**. In the implanted configuration, a distal end of the anti-rotation screw **20** is separated from a distal end of the implant shaft **130** by approximately 5 mm. As shown in FIGS. **61-63**, the first protection sleeve **60** is then inserted through the first opening **1247** in the insertion instrument **1240**. As described in greater detail in earlier embodiments, the first protection sleeve **60** extends through the first opening **1247** and into the distal end **46** of the insertion instrument **40** at a predetermined angle relative to the angle of the first elongated shaft portion **1252** (e.g., 45°, etc.) until a distal end thereof is in contact with the locking hole **108**, as shown in the partial cutaway view of FIG. **62**. An optional drilling mechanism known in the art may be inserted through the first protection sleeve **60** to drill an opening through the locking hole **108** of the bone plate **102** and into the bone. The drilling mechanism may then be removed and the bone fixation element **10** may be inserted through the first protection sleeve **60** and bone plate **102** and into the bone **1**. The first protection sleeve **60** and instrument **1240** may then be removed, leaving the system **100** implanted in the bone. It is noted that although the exemplary method depicts the insertion of the anti-rotation screw **20** followed by the bicortical screw **10** first, the order of insertion may be changed without deviating from the scope of the invention to suit, for example, a surgeon's preference. Furthermore, although the kit **1200** is described with respect to the system **100**, the kit **1200** may be employed with any of the systems **200**, **300**, **400**, **500**, **600**, **800** disclosed herein.

It will be appreciated by those skilled in the art that various modifications and alterations of the invention can be made without departing from the broad scope of the appended claims. Some of these have been discussed above and others will be apparent to those skilled in the art.

What is claimed is:

1. A device for implanting a bone fixation system, comprising:

an insertion instrument including an arm and a shaft coupled to the arm, the shaft extending from a proximal end to a distal end, the distal end having an engagement portion for removably engaging a proximal end of a bone plate, the arm having an elongated channel extending therethrough along a channel longitudinal axis to permit insertion of a first protection sleeve therethrough wherein the channel longitudinal axis is coaxial with a longitudinal axis of a first opening extending through the bone plate and wherein the channel longitudinal axis is angled with respect to a longitudinal axis of the shaft; and

a first protection sleeve insertable through the elongated channel and into a distal portion of the insertion instrument, the first protection sleeve guiding insertion of an anti-rotation screw therethrough and through the bone plate, a longitudinal axis of the first protection sleeve being angled with respect to the longitudinal axis of the elongated channel.

2. The device of claim **1**, wherein the first protection sleeve and the elongated channel enclose an angle of one of 5°, 6°, 7.5° and 8°.

3. The device of claim **1**, wherein the first protection sleeve and the elongated channel enclose an angle greater than 5°.

4. The device of claim **1**, further comprising a second protection sleeve insertable into the insertion instrument and guiding insertion of a locking screw therethrough and into a second opening in the bone plate.

5. The device of claim **4**, wherein the second protection sleeve and the elongated channel enclose an angle of approximately 45°.

6. The device of claim **4**, wherein the insertion instrument includes an arm extending away from the proximal end, the arm including an opening extending therethrough to guide insertion of the second protection sleeve.

7. The device of claim **1**, further comprising an elongated shaft portion connected to the first protection sleeve, the elongated shaft portion being insertable into the elongated channel.

8. The device of claim **7**, wherein a proximal end of the elongated shaft portion includes a locking mechanism to lockingly engage the insertion instrument.

9. The device of claim **8**, wherein the locking mechanism includes a deflectable tab configured to engage a corresponding opening formed in the insertion instrument with a snap-fit.

10. The device of claim **8**, wherein the locking mechanism includes a threaded portion and a screw mechanism, wherein rotation of the screw mechanism a rotation of the elongated shaft relative to the first protection sleeve to permit the threaded portion to threadedly engage a corresponding threaded opening in the insertion instrument.

11. The device of claim **7**, wherein the elongated shaft portion is connected to the first protection sleeve via a Y-connector.

12. The device of claim **1**, wherein a side wall of the insertion instrument includes an elongated slot open to the elongated channel, the slot permitting insertion of a Y-connector therepast.

13. The device of claim **1**, wherein the device is a single-use assembly.

14. The device of claim **1**, wherein the device may be used to perform a plurality of procedures.

15. The device according to claim **1**, wherein, when coupled to a bone plate, the longitudinal axis of the shaft is

aligned with an axis of a hole in the bone plate through which a trochanteric implant is to be inserted.

16. An aiming instrument to guide insertion of a bone fixation device into a bone, comprising:

an aiming arm including a first portion and a second portion, the first portion extending from a proximal end to a distal end and having an elongated channel extending therethrough, the distal end having an engagement portion removably engaging a proximal end of the bone fixation device, a side wall of the aiming arm including an elongated slot open to the elongated channel; and

an elongated element removably insertable into the elongated channel, the elongated element having a first shaft portion and a second shaft portion, the first shaft portion being inserted into the elongated channel and lockingly engaging the aiming arm, the second shaft portion extending through the elongated slot and having an opening extending therethrough to guide insertion of an anti-rotation screw therethrough and into the bone fixation device, a longitudinal axis of the second shaft portion being angled with respect to a longitudinal axis of the elongated channel.

17. The aiming instrument of claim **16**, further comprising a protection sleeve insertable through the opening toward the distal end of the first portion such that a distal end of the protection sleeve is positioned adjacent to a proximal end of the bone fixation device.

18. A method of implanting a bone fixation device into a bone, comprising:

engaging a distal end of a guide assembly to a proximal end of a bone fixation device so that a first portion of the guide assembly having an elongated channel extending therethrough is coaxial with a longitudinal axis of the bone fixation device, wherein the first portion extending from a proximal end to a distal end;

inserting an elongated shaft portion through the elongated channel and into a distal portion of the guide assembly, the elongated shaft portion including a first protection sleeve;

inserting the bone fixation device into a shaft of the bone so that a first portion of the bone fixation device is positioned over an outer surface of the bone and a second portion of the bone fixation device is received within the bone; and

inserting an anti-rotation screw through the first protection sleeve until a shaft of the anti-rotation screw extends out of the bone fixation device at an angle offset from the longitudinal axis of the bone fixation device.

19. The method of claim **18**, wherein the implanted anti-rotation screw is offset from the longitudinal axis of the bone fixation device by approximately 7.5°.

20. The method of claim **18**, further comprising the step of inserting a second protection sleeve through an opening formed in a second portion of the guide assembly and inserting a locking screw through the second protection sleeve and bone fixation device and into the bone.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO.	: 9,314,283 B2
APPLICATION NO.	: 13/805919
DATED	: April 19, 2016
INVENTOR(S)	: Overes et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In the Claims

Claim 10, Column 18, Line 51:
"rotation of the screw mechanism a rotation of the elongated" should read "rotation of the screw mechanism causes a rotation of the elongated".

Signed and Sealed this
Twenty-first Day of June, 2016

Michelle K. Lee

Michelle K. Lee
Director of the United States Patent and Trademark Office